#### REDACTED DOCUMENTS RELATING TO DOCKET 7315

EXHIBIT A – Previously filed redacted in DKT 8118

EXHIBIT B – No redactions

EXHIBIT C - No redactions

EXHIBIT D – Previously filed redacted in DKT 8118

EXHIBIT E – Previously filed redacted in DKT 8118

#### **EXHIBIT B**



# Deposition of: **Robert McMeeking , Ph.D.**

July 6, 2017

In the Matter of:

In Re: Bard IVC Filters Products
Liability

#### Veritext Legal Solutions

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	Page 1
1	IN THE UNITED STATES DISTRICT COURT
2	FOR THE DISTRICT OF ARIZONA
3	
4	
5	IN RE BARD IVC FILTERS CASE NO.
6	PRODUCTS LIABILITY LITIGATION MD-15-02641-PHX-DGC
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21	VIDEOTAPED DEPOSITION OF ROBERT M. McMEEKING, Ph.D.
22	
23	THURSDAY, JULY 6, 2017
24	
25	REPORTED BY: MONICA T. CORLEY, CSR NO. 8803

Veritext Legal Solutions

	In Ke: Bard IVC Fin	ers	Froducts Liability	
1 2 3 4 5 6 6 7 8 9 10 11 12 13 14	Page 2 VIDEOTAPED DEPOSITION OF ROBERT M. McMEEKING, Ph.D., THE WITNESS, TAKEN ON BEHALF OF THE DEFENDANTS, AT 9:06 A.M., THURSDAY, JULY 6, 2017, AT 401 STORKE ROAD, GOLETA, CALIFORNIA, BEFORE MONICA T. CORLEY, CMR, CRR, CSR NO. 8803.  APPEARANCES OF COUNSEL  FOR PLAINTIFFS: GALLAGHER & KENNEDY, P.A. BY: MARK S. O'CONNOR, ESQ. 2575 EAST CAMELBACK ROAD PHOENIX, ARIZONA 85016-9225 (602) 530-8000 MARK.OCONNOR@GKNET.COM	Ι.	EXHIBITS (CONTINUED) NO. PAGE DESCRIPTION  EXHIBIT 7 5 REPORT ON THE BARD INFERIOR VENA CAVA FILTER IMPLANTED IN MS. SHERRA-UNA BOOKER  EXHIBIT 7A 282 HURST REPORT ON BOOKER  EXHIBIT 7B 282 MUEHRCKE REPORT ON BOOKER  EXHIBIT 8 5 REPORT ON THE BARD INFERIOR VENA CAVA FILTER IMPLANTED IN MS. LISA ANN HYDE  EXHIBIT 8A 282 HURST REPORT ON HYDE EXHIBIT 8A 282 HURST REPORT ON HYDE EXHIBIT 8B 282 MUEHRCKE REPORT ON HYDE EXHIBIT 8B 282 HURST REPORT ON HYDE EXHIBIT 9 5 REPORT ON THE BARD INFERIOR VENA CAVA FILTER IMPLANTED IN MRS. DORIS Y. JONES	Page 4
15		15	ENTINET OA AOS IN HOT DEPLOY ALLIANDA	
16		16	EXHIBIT 9A 282 HURST REPORT ON JONES	
	FOR DEFENDANTS		EXHIBIT 9B 282 MUEHRCKE REPORT ON JONES	
17	NOT CONTACT TO THE PARTY OF COMPANY OF COMPANY	17	EXHIBIT 10 5 INFERIOR VENA CAVA FILTER	
18	NELSON MULLINS RILEY & SCARBOROUGH, LLP BY: TAYLOR TAPLEY DALY, ESQ. 201 17TH STREET	18	IMPLANTED IN MS. CAROL KRUSE	
19	SUITE 1700		EXHIBIT 10A 282 HURST REPORT ON KRUSE	
1	ATLANTA, GEORGIA 30363	20	EXHIBIT 10B 282 MUEHRCKE REPORT ON KRUSE	
20	(404) 322-6000 TAYLOR.DALY@NELSONMULLINS.COM	21	EXHIBIT 11 S INFERIOR VENA CAVA FILTER IMPLANTED IN MS. DEBRA	
21			MULKEY	
22	AT CO DDECEME.	23	EXHIBIT 11A 282 HURST REPORT ON MULKEY	
23 24	ALSO PRESENT: GEOFF MINGER, VIDEOGRAPHER	24		
25	SECTION INDUSTRIES	25	EXHIBIT 11B 282 MUEHRCKE REPORT ON MULKEY	
1 2 3 4 5 6 7 8	Page 3  INDEX  WITNESS EXAMINATION PAGE ROBERT M. McMEEKING, Ph.D.  BY MS. DALY 8, 325  (P.M. SESSION) 170  BY MR. O'CONNOR 303, 334	1 2 3 4 5 6	EXHIBITS (CONTINUED)  NO. PAGE DESCRIPTION  EXHIBIT 12 46 CLINICAL STUDY ENTITLED  "ANALYSIS OF THE FINAL  DENALI TRIAL DATA: A  PROSPECTIVE, MULTICENTER  STUDY OF THE DENALI  INFERIOR VENA CAVA FILTER"  BY STAVROPOULOS, ET AL.	Page 5
9		7	EXHIBIT 13 64 ARTICLE ENTITLED	
10		8	"RESPIRATORY-INDUCED	
11	EXHIBITS	9	HAEMODYNAMIC CHANGES: A CONTRIBUTING FACTOR TO IVC	
13	NO. PAGE DESCRIPTION	10	FILTER PENETRATION, BY	
14		11	LABORDA, ET AL. EXHIBIT 14 93 ARTICLE ENTITLED	
15	EXHIBIT 1 5 CURRICULUM VITAE	12	"EVALUATION OF WALL MOTION AND DYNAMIC GEOMETRY OF THE INFERIOR VENA CAVA	
16	EXHIBIT 2 5 ASSESSMENT OF THE DESIGNS OF BARD INFERIOR VENA CAVA	13	USING INTRAVASCULAR ULTRASOUND," BY MURPHY, ET AL.	
17	FILTERS: THE RECOVERY, G2, G2 EXPRESS, ECLIPSE, MERIDIAN AND DENALIS	15	EXHIBIT 15 93 ARTICLE ENTITLED "INFLUENCE OF BREATHING MOVEMENTS AND VALSALVA	
18	BY McMEEKING		MANEUVER ON VENA CAVAL	
19	EXHIBIT 3 5 SUPPLEMENTARY REPORT BY	17	DYNAMICS," BY LABORDA, ET AL.	
	McMEEKING, DATED 4-7-17	18		
20	EXHIBIT 4 5 REBUTTAL REPORT BY	19	EXHIBIT 16 155 EXCERPT ON BARD DENALI FILTER FRACTURES, BY MAIDALANY, ET AL.	
21	McMEEKING, DATED 5-11-17	20		
22	EXHIBIT 5 5 11-6-16 INVOICE TOTALING	21	EXHIBIT 17 180 ARTICLE ENTITLED "A STATISTICAL APPROACH TO	
23	\$14,800		UNDERSTAND THE ROLE OF	
	EXHIBIT 5A 5 11-6-16 INVOICE TOTALING	22	INCLUSIONS ON THE FATIGUE RESISTANCE OF SUPERELASTIC	
24	\$5,200	23	NITINOL WIRE AND TUBING," BY ROBERTSON, ET AL.	
25	EXHIBIT 6 5 4-18-17 INVOICE TOTALING \$51,400	24 25	DI NOBEREDOLY DE PER	

	In Re: Bard IVC Fill		
	Page 6		Page 8
1	EXHIBITS (CONTINUED)	1	defendants.
2 3	NO. PAGE DESCRIPTION	2	THE VIDEOGRAPHER: Those present on the
3	EXHIBIT 18 208 ARTICLE ENTITLED	3	phone.
4	"LONG-TERM RESULTS OF TH	E 4	MS. DALY: They don't make appearances.
'	SIMON NITINOL INFERIOR	5	MR. O'CONNOR: They don't need to make
5	VENA CAVA FILTER," BY	6	appearances.
	POLETTI, ET AL.	7	THE VIDEOGRAPHER: Okay. The witness will
6		8	be sworn in, and Counsel may begin the examination.
7		9	
8		10	ROBERT M. McMEEKING, Ph.D.,
9		11	having been first duly sworn, was
10 11		12	examined and testified as follows:
12		13	
13		14	EXAMINATION
14		15	BY MS. DALY:
15		16	Q Dr. McMeeking, we've met several times
16		17	before.
17		18	A Yes, we have.
18		19	Q How are you today?
19		20	A Very well, thank you.
20		21	Q Good,
21 22		22	I went ahead and premarked a couple of
23		23	things before we started the deposition, so let's
24		24	just go through those.
25		25	The first item is marked Exhibit 1, and
	Page 7		Page 9
1	GOLETA, CALIFORNIA;	1	that is a new updated curriculum vitae that you
2	THURSDAY, JULY 6, 2017, 9:06 A.M.	2	handed me this morning, correct?
3		3	A That's correct.
4	(Whereupon, Deposition Exhibits 1 through	4	Q Can you tell me what areas include
5	11 were pre-marked for identification by	5	something new?
6	the Court Reporter.)	6	A There's three areas. There's a few papers
7	·	7	that I've added to the list of publications. I
8	THE VIDEOGRAPHER: Good morning.	8	have a new title at UCSB, although that may be on
9	We are on the record at 9:06 a.m. on July	9	the last curriculum vitae that I submitted, because
10	6, 2017. This is the video recorded deposition of	10	in addition to being emeritus professor of
11	Robert McMeeking, Ph.D.	11	structural materials, I'm distinguished professor
12	My name is Geoff Minger, here with our	12	of mechanical engineering and distinguished
13	court reporter Monica Corley. We are here from	13	professor of materials. And then the third area
14	Veritext Legal Solutions.	14	where there is an addition is that I have been
15	This deposition is being held at 401	15	elected the president of the International Congress
16	Storke Road in Goleta, California. The caption of	16	on Fracture, which actually happened last month, so
17	the case is In Re: Bard IVC Filters Liability	17	I'm the president of that organization for four
18	Litigation filed in the United States District	18	years.
19	Court for the District of Arizona, Case	19	Q On your three new papers, what do they
20	No. MD-15-02641-PHX-DGC.	20	talk about?
21	Would Counsel please identify themselves	21	A It may not be three new papers but I
22	for the record, and state their appearances.	22	didn't count how many new papers there are, but
23	MR. O'CONNOR: Yes. My name is Mark	23	there's a number of new papers, and they outline
24	O'Connor, and I represent the plaintiffs.	24	I need to refer to the list to
25	MS. DALY: I'm Taylor Daly for the Bard	25	Q Sure.
44	M.S. DALI. III I aylor Dary for the Dalid	رع	ζ pme.

	In Re: Bard IVC Filt	CIS I	Toducis Diability
	Page 10		Page 12
1	A give you that information.	1	on that invoice and through what period of time.
2	There is one on adhesion, there's one on	2	A The work represented in this invoice is in
3	plasticity in high temperature nickel-based alloys,	3	connection with the Bard MDL cases and is for
4	there's one on the behavior of materials called	4	expert witness work for the plaintiff, or the
5	hydrogels, there's one on calculations for lithium	5	plaintiffs, and the dates involved range from 18th
6	ion batteries, and there's a number of other	6	of January 2017 to the 2nd of April 2017.
7	similar papers but they're all along those lines in	7	Q Okay. Now, is there work that you have
8	terms of the areas which are involved.	8	done since the time of that invoice?
9	Q Are any of them relating to nitinol	9	A Yes.
10	materials?	10	Q And what period of time and approximately
11	A No.	11	how much have you billed?
12	Q Or to IVC filters?	12	A Well, from the 3rd of April 2017 I have
13	A No.	13	not billed that, that time.
14	Q Okay. Thank you.	14	Q Okay.
15	All right. Then I marked as Exhibit 2	15	A But the dates are from the 3rd of April
16	what I call your main report in the MDL litigation	16	2017 to yesterday, and the number of hours involved
17	that's dated 3-17 of 2017, correct?	17	is approximately 110.
18	A I need to look at the date, which is in	18	Q What did you do for preparation for your
19	the middle of the report. Page March the 3rd,	19	deposition today?
20	2017.	20	A I reviewed a number of documents,
21	Q Oh, sorry. Okay.	21	including the reports that you have marked as
22	A Yeah.	22	exhibits, and then I read a number of papers that
23	Q March the 3rd. All right.	23	are connected to the case, these are scientific
24	And then what I've marked as Exhibit 3 is	24	papers that are connected to the case, and I read
25	the Supplementary Report specific to Meridian and	25	expert reports of individuals appearing for the
	Page 11		Page 13
1	Denali that's dated at the top April 7, 2017,	1	defense and individuals appearing for the
2	correct?	2	plaintiffs.
3	A Correct.	3	Q Which individuals for the Bard did you
4	Q And then I marked as Exhibit 4 a report by	4	read in preparation for today?
5	you called Rebuttal Report dated May 11, 2017?	5	A I read the reports by Dr. Fasching. I
6	A Correct.	6	read the reports by Dr. Briant.
7	Q All right. Now, let me go ahead and show	7	Q Anybody else?
8	you what I've marked 5, 5A and 6. 5 and 5A are	8	A Well, in the past I've read reports by
9	copies of bills that you gave me, where the bills	9	medical experts who provided reports in connection
10	are dated November 6, 2016; and Exhibit 6 is a bill	10	with case-specific individuals, but I did not
11	dated April 18, 2017.	11	review them in the last few last week or so
12	Starting with 5 and 5A, would you just	12	Q Okay.
13	tell me basically what work was that that was being	13	A for the deposition.
14	done and through what time frame?	14	Q Now, I'm going to show you, just while
15	A The work on that was in regard to the case	15	we're talking about exhibits that we're getting on
16	Austin versus Bard and it was expert witness work	16	the record, I've marked as 7, 8, 9, 10 and 11 five
17	for the plaintiff, and the time involved ranges	17	case-specific reports that you did in the
18	from the 8th of April 2016 to the 31st of August	18	Bellwether cases. So 7 is on Ms. Booker's case.
19	2016.	19	If you just confirm "yes" when I hand these to you.
20	Q All right. And then 5A, what is that?	20	A Yes, that's correct.
	A 5A is the bill I submitted for a	21	Q 8 is in Mrs. Hyde's case?
21			- ·
	deposition that took place on 19th of July 2016 in	22	A Yes, that's correct.
21		22 23	
21 22	deposition that took place on 19th of July 2016 in		A Yes, that's correct.

	In Re: Baru IVC File		<u> </u>
1 _	Page 14	١.	Page 16
1	A Yes, that's correct.	1	medical implant devices.
2	Q And 11 is Debra Mulkey?	2	Q Does it direct or regulate the FDL?
3	A Yes, that's correct.	3	A The FDA?
4	Q Did you read any case-specific reports of	4	Q The FDA.
5	any expert for Bard or the plaintiffs in connection	5	A No. No.
6	with your work in writing those case-specific	6	Q It does not establish their regulations?
7	reports or in preparation for today's deposition?	7	A It does not establish their regulations.
8	A Yes. In in preparation for writing the	8	Q Does it oversee them in any way?
9	case-specific reports, I consulted reports by	9	A Not to my knowledge.
10	Dr. Darren Hurst, Dr. Derrick Muehrcke, and	10	Q Okay. And to what industries does it
11	Dr. Robert Richie.	11	apply? You said medical devices?
12	Q So Hurst, Muehrcke and Richie?	12	A Medical implant devices.
13	A Correct. Yes.	13	Q So it has to be medical and implantable?
14	Q For the case specific?	14	A I believe so.
15	A Yes.	15	MR. O'CONNOR: Form. Foundation.
16	Q Okay. Did you see any Bard medical	16	THE WITNESS: It may cast a wider remit,
17	case-specific reports?	17	but I don't know whether other devices and systems
18	A On those individuals?	18	are involved.
19	Q On those individuals.	19	BY MS. DALY:
20	A No.	20	Q Okay. Has the United States FDA formally
21	MR. O'CONNOR: Object to the form.	21	adopted the standards for application to devices
22	BY MS. DALY	22	that fall under the FDA's jurisdiction?
23	Q Okay. What reports have you read of	23	MR. O'CONNOR: Form and foundation.
24	plaintiffs' experts in preparation for today?	24	THE WITNESS: Not to my knowledge.
25	A I read reports by Dr. Richie. I read	25	BY MS. DALY:
[	Page 15		Page 17
1	reports by Dr. Parisian and by Dr. Kessler. And I	1	Q Has the FDA formally issued any comments
2	should say that I also read, in preparation for the	2	on the applicability of those standards to medical
3	case, some transcripts of depositions, which I	3	devices it has jurisdiction over?
4	didn't mention before.	4	MR. O'CONNOR: Form and foundation.
5	Q And who did you read transcript-wise?	5	THE WITNESS: Not to my knowledge.
6	A I read transcripts of depositions of	6	BY MS. DALY:
7	Dr. Fasching. I read an old not old, a	7	Q Has the FDA ever stated that medical
8	deposition in the Austin case by Dr. Briant. I	8	devices presented to it via 510(k) submissions must
9	read deposition by Dr. Richie. And I believe	9	follow the standards of IMDRF/GHTF?
10	that's it.	10	MR. O'CONNOR: Form and foundation.
11	Q Okay. All right. I'm going to start with	11	THE WITNESS: Not to my knowledge.
12	Exhibit 2, which is your main report.	12	BY MS. DALY:
13	All right. So Exhibit Exhibit 2, your	13	Q Section 3.2.1 in paragraph I of your
14	March 2017 MDL report, on page 5, that references	14	report states "Medical devices should be designed
15	the IMDRF/GHTF standards?	15	and manufactured so they will perform as intended
16	A Correct.	16	by the manufacturer and not compromise the clinical
17	Q In your Section 3.2.1, right?	17	condition or safety of patients."
18	A Yes, that's right.	18	Did I read that right?
19	Q All right. What is the IMDRF/GHTF?	19	A Well, it says "for the purposes intended
20	A It's an international organization that	20	and where applicable." I don't see where it says
21	coordinates regulatory not so much coordinating	21	"by the manufacturer." But other than that, I
22	regulatory affairs but coordinates the activities	22	agree with your reading of the sentence.
23	of regulators and industrial participants and	23	Q Okay. And you agree with me that's a very
24	academics in terms of processes, procedures and	24	general statement about product development and
25	concepts that are relevant to the regulation of	25	manufacture?

Page 18 1 A Well, yes. 2 MR, O'CONNOR: Form. 3 THE WITNESS: And it — it would apply to more than just medical implant devices. 5 BY MS, DALY: 6 Q And what I just read, is that a direct quote from the standards or is that a summarization of yours? 9 A Well, as far as I remember, it's a direct quote. But let me read. 10 quote, But let me read. 11 Q I only ask that because it doesn't have quotes around it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my recollection, a direct quotes around; it. That's — it is, to my required a might inoticate that a manufacturer alound approach that with when risk reduction is required might indicate that a manufacturer should look at that situation?  12 A May I look?  12 A Well, I looked at a specific page to obtain those paragraphs.  13 A Well, I looked at a specific page to obtain those paragraphs.  14 Q O Ckay.  24 A Well, I looked at a specific page to obtain those paragraphs.  15 Page 19  1 Q O Ckay.  2 A Yes, Ves.  2 Q O Ckay. Paragraph 2, moving on in your report, states that "When risk reducti	_	III Re. Data IVE Photos Flacinity			
THE WITNESS: And it — it would apply to more than just medical implant devices.  BY MS. DALY:  quote from the standards or is that a direct quote from the standards or is that a summarization of yours?  A Well, as far as I remember, it's a direct quote. But let me read.  Q I only ask that because it doesn't have quotes around it. That's —  A Oh, yeah, it's — it is, to my recollection, a direct quote from the principles, which are enunciated by what is now GHTF.  Q You did not cite to an exact portion of those standards in this paragraph 1.  A I —  Q I not her words, I don't have a page, I don't have a section from the GHTF —  A May I look?  A Well, I looked at a specific page to obtain those paragraphs.  Page 19  Q Okay.  Page 19  Q Okay.  Page 19  Q Okay.  A — in the list of references, and there's information there which is involved. Namely, the find the page which is involved. Namely, the standards generally?  A Yes, Yes.  Q All right. "Should identify known or foreseeable hazards and estimate the associated risks arising from the intended use," I'm skipping forward a little bit, "eliminate risks as far as reasonably practical through inherently safe design and form users of risks in the remaining risk by taking adequate protection measures, including alarms and inform users of risks in their report, states that "When risk reduction is required" on you see that sentence — that — go what how that, for example, Bard submitted with its products?  A Yes, Yes.  Q Okay. Paragraph 2, moving on in your report, states that "When risk reduction is required" on you see that sentence — that — go what does that mean, "When risk reduction is required" on you see that sentence — that — go what does that mean, "When risk reduction is required" and an unaffacturer and a little bit, "eliminate risk as far as reasonably practicable the remaining risk by taking adequate protection measures, including alarms and inform users of risks in their products. What I'm not aware of is whether they fally informed the users of the risks.	1	<del>-</del>		•	
THE WITNESS: And it—it would apply to more than just medical implant devices.  BYMS. DALY:  Q And what I just read, is that a direct quote from the standards or is that a direct quote from the standards or is that a summarization of yours?  A Well, as far as I remember, it's a direct quote. But let me read.  Q I only ask that because it doesn't have quotes around it. That's—  A Oh, yeah, it's—it is, to my recollection, a direct quote from the principles, which are enunciated by what is now GHTF.  Q You did not cite to an exact portion of those standards in this paragraph 1.  A I—  A May I look?  Q — that I could go to. Do you know if you did that?  A Well, I looked at a specific page to obtain those paragraphs.  Page 19  Q Okay.  A Well, I looked at a specific page to obtain those paragraphs.  Page 19  Q Okay.  A Well, I looked at a specific page to obtain those paragraphs.  Page 19  Q Okay.  A Well, I looked at a specific page to obtain those paragraphs.  Page 19  A Well, I looked at a specific page to obtain those paragraphs.  Page 19  A Well, I looked the form of the question.  BY MS. DALY:  Q And that when risk reduction is required might indicate that a manufacturer should look at that situation?  A I would agree with that statement.  MR. O'CONNOR: Object to the form of the question.  A I would agree with that statement.  MR. O'CONNOR: Object to the form of the question.  A I would agree with that statement.  MR. O'CONNOR: Object to the form of the question.  A Yes, Yes.  Q All right. Paragraph 2 goes on to say at the fifth line there that "A manufacturer should identify known or foresceable hazards and estimate the associated risks arising from the intended use," I'm skipping forward a little bit, "eliminate risks as far as reasonably practical through inherently safe design and manufacture, reduce as far as reasonably practical through inherently safe design and manufacturer, reduce as far as reasonably practically through inherently safe design and manufacture, reduce as far as reasonably practically th				=	
4 more than just medical implant devices. 5 BY MS. DALY: 6 Q And what I just read, is that a direct quote from the standards or is that a summarization of yours? 9 A Well, as far as I remember, it's a direct quote. But let me read. 10 quote. But let me read. 11 Q I only ask that because it doesn't have quotes around it. That's 12 A Oh, yeah, it's it is, to my recollection, a direct quote from the principles, which are enunciated by what is now GHTF- 15 Which are enunciated by what is now GHTF- 16 Q You did not cite to an exact portion of those standards in this paragraph 1. 18 A I 19 Q In other words, I don't have a page, I quotes are collection, a direct quote from the GHTF 21 A May I look? 22 Q that I could go to. Do you know if you did that? 24 A Well, I looked at a specific page to obtain those paragraphs.  Page 19 Q Okay. 2 A So it references 9 2 Q Ub-buh. 3 Q Ub-buh. 4 A in the list of references, and there's information there which I believe will enable me to find the page which is involved. Namely, the information there which I believe will enable me to find the page which is involved. Namely, the standards generally? 2 A Yes.  9 Gkay. Paragraph 2, moving on in your report, states that "When risk reduction is required might indicate that a manufacturer should look at that situation?  10 Q In other words, I don't have a page, I don't have a section from the GHTF 21 A May I look? 2 Q Q that I could go to. Do you know if you did that? 2 A So it references 9 3 Q Ub-buh. 4 A in the list of references, and there's information there which I believe will enable me to find the page which is involved. Namely, the intended use, "I'm skipping forward a little bit, "eliminate risks as far as a some of any residual risks."  10 G Vay. And I was just asking, did you cite anything more specific, like it's page I0, section such-and-auch? You justyou just cited to the standards generally? 2 A Yes. 3 Q Okay. Paragraph 2, moving on in your report, states that "When risk reduction is requi	1				
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2	Q And do you also understand that the FDA	2	able to reduce as far as reasonably practical
3	reviewed and approved those IF Use and dear doctor	3	practicable by taking adequate protection measures
4	letters?	4	any of those risks you just identified?
5	MR. O'CONNOR: Form. Foundation.	5	MR. O'CONNOR: Form and foundation.
6	THE WITNESS: I don't know of that for a	6	BY MS. DALY:
7	fact in this particular case, but I I assume	7	Q In filters.
8	that that is the process which is involved.	8	A I have not investigated that in many
9	BY MS. DALY:	9	cases, and in other cases I'm under restrictions in
10	Q And then backing up to the prior statement	10	terms of what I can say when I have been involved
11	in that paragraph, that "The manufacturer should	11	in investigating that.
12	reduce as far as reasonably practicable the	12	Q Do you rely on any of the work that you
13	remaining risks by taking adequate protection	13	have done that you cannot talk to me about for you
14	measures," what risks associated with Bard filters	14	opinions in this case?
15	do you think Bard needed to reduce as reasonably	15	A No.
16	practicable?	16	MR. O'CONNOR: Form.
17	A I think they should have tried to reduce	17	BY MS. DALY:
18	the risks of tilting, perforation, migration and	18	Q So anything that you have learned either
19	fracture by fatigue.	19	as a consulting expert or a retained expert with
20	Q Are those risks that you've just	20	respect to other IVC filters you do not rely on for
21	identified risks that are known to be associated	21	your opinions in the Bard litigation?
22	with all IVC filters?	22	A Yeah, I do not rely on that other
23	MR. O'CONNOR: Form and foundation.	23	information.
24	THE WITNESS: As far as I know, there are	24	Q Okay. And I'm aware that you've been
25	such risks in many of the filters which are on the	25	retained in the Cook litigation.
	Page 23		Page 25
1	market.	1	A That's correct, yes.
2	BY MS. DALY:	2	Q Because that's been public. Okay.
3	Q Is it your opinion that Bard failed to	3	I think you just said a moment ago that
4	reduce as far as reasonably practicable the	4	with respect to all of Bard's retrievable filters,
5	remaining risks by taking adequate protection	5	that is from the Recovery to the Denali, that it is
6	measures?	6	your opinion that Bard has not done what is
7	A Can you repeat the question, please.	7	reasonably practicable to take adequate protection
8	Q Yes.	8	measures against tilt, perforation, migration and
9	Is it your opinion that Bard failed to	9	fracture?
10	reduce as far as reasonably practicable the	10	A That's correct.
11	remaining risks by taking adequate protection	11	Q Okay. Is it your opinion that the various
12	measures?	12	modifications that Bard has made along the way to
13	MR. O'CONNOR: Form and foundation.	13	its retrievable IVC filters did nothing to reduce
14	THE WITNESS: In certain of the designs of	14	the risks associated with either tilt, perforation,
15	the filters those risks, in my opinion, were not	15	migration or fracture?
16	reduced to the extent practicable, and I would say	16	MR. O'CONNOR: Form.
17	that that applies to all of the models that we are	17	THE WITNESS: The some of the changes
18	discussing in the in the present case.	18	that were made would have some effects on one or
19	BY MS. DALY:	19	more of those phenomena that can take place in
20	Q And which risks do you identify that	20	filters, and in some cases it's unclear whether the
	you have an opinion that Bard failed to reduce?	21	measure taken had the effect intended, but but
21	4 604 1.1 6.11.1 6 .1	22	there would have been some benefits from some of
21 22	A The risks of tilting, perforation,		
21 22 23	migration and fracture by fatigue.	23	the changes which were made.
21 22		23	

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1	from the G2X, Eclipse, Meridian or Denali models?	1	MR. O'CONNOR: Form and foundation.
2	A I've modeled the G2X. I have modeled all	2	THE WITNESS: I have not done any
3	of the filters in the sense that I've made the	3	calculations that specifically identify the
4	assessment that they all have similar	4	detailed differences that would occur because of
5	characteristics and, therefore, in certain of the	5	the design changes going from the G2X through to
6	aspects of the behavior, the response will be the	6	the Denali.
7	same will be very similar in each of the	7	BY MS. DALY:
8	filters.	8	Q So going back to the language of the
9	Q When you say "model," with respect to the	9	standard, on what do you base your opinion that
10	G2X on to the Denali, you've looked at design	10	Bard has not done what is reasonably practicable to
11	drawings, correct?	11	take appropriate protection measures in any of its
12	A Correct.	12	retrievable filters against the complications that
13	Q And you've taken you've looked at the	13	you identified?
14	measurements of the, you know, length of legs or	14	A Well, part of the issue is that they
15	width of legs, those sorts of things, correct?	15	should have taken certain measures sooner than they
16	A Well, I've relied on the engineering	16	ultimately did and that the measures that they
17	drawing to give me the values of those lengths.	17	eventually took were πot necessarily effective at
18	Q So in that sense you've you've modeled	18	reducing the risk to the extent practicable and
19	from the design drawings, correct?	19	they didn't investigate the consequences they
20	A Well, I should I should clarify my	20	didn't investigate thoroughly the consequences of
21	response.	21	the trade-offs that were involved in the design
22	I have looked at those drawings and I've	22	changes to modify the filters from the G2
23	compared all the filters with each other in terms	23	through G2X through to the Denali.
24	of their size and shape and so on, and then that	24	Q How would they have done that differently?
25	has allowed me to make a deduction that my modeling	25	A Well, they would have done more
	Page 27		Page 29
1	of the G2 and the G2X is representative of the	1	investigations of the behavior in bench tests and
2	behavior that one would expect to see in the models	2	they would they should have designed bench tests
3	namely the Eclipse, the Meridian and the Denali.	3	that were more effective at investigating the
4	Although not exactly the same, there would be	4	behavior that you would expect to see in the filter
5	similar behavior in each of these other three	5	when it was eventually implanted in the in
6	filters.	6	patients. And they perhaps should have done animal
7	Q Have you done any FEAs specific to the	7	tests as well, but I will not comment specifically
8	Eclipse, the Meridian or the Denali?	8	on what those animal tests should have been.
9	A I have not done FEA analysis specific to	9	Q And you haven't yourself done any further
10	the Eclipse, Meridian and Denali.	10	investigations beyond what Bard did to see if you
11	Q And you have not done work that would tell	11	can determine, through investigation, whether Bard
12	you what the specific modifications of filters that	12	in fact failed to understand or determine some
13	Bard has has included would do with respect to,	13	characteristic in their filter that was leading to
14	for example, loads on the filter, strains that the	14	complications?
15	filter is	15	MR. O'CONNOR: Object to the form of the
16	A I have not	16	question.
17	MR. O'CONNOR: Form and foundation.	17	THE WITNESS: I I have not done such
18	BY MS. DALY:	18	investigations.
19	Q Let me finish.	19	BY MS. DALY:
20	MR, O'CONNOR: Let her finish the	20	Q And you also have not developed any bench
21	question.	21	testing that you think would have been better
22	BY MS. DALY:	22	testing that Bard could have done to reveal
23	Q Let me finish.	23	something about their filter that identified
24	strains that the filter sees or loads	24	information about these complications?
25	that are put on those filters?	25	A I don't do bench testing, so no, I haven't

	In Re. Baid IV C Priters Froducts Liability				
1	Page 30 developed any bench tests.	1	Page 32 THE WITNESS: I've I've not		
2	Q And you just said you hadn't done any	2	investigated that aspect of the situation, and as I		
3	animal testing and you didn't	3	said before, I defer to Dr. Richie in regard to		
4	A No.	4	electropolishing wires.		
5	Q have any ideas of protocols?	5	BY MS. DALY:		
6	A I don't do animal testing and I	6	Q Are there any other changes that you think		
7	Q Okay. With respect to the comment you	7	Bard later made to its filters that it could have		
8	just made about Bard should have taken certain	8	made earlier		
9	measures sooner, we've talked about some of these	1	A Yes.		
10	before. The electropolishing issue, for example,	10	Q to to impact resistance to		
11	you've testified before that you thought they	11	complications?		
12	should have done that earlier?	12	A Yes.		
13	A I believe I said I rely on prof	13	Q All right. And what are those?		
14	Dr. Richie in regard to the question of	14	A They could have developed caudal anchors		
15	electropolishing the wires that are in the filters.	15	sooner than they ultimately did. They could have		
16	Q Okay. So with respect to an opinion that	16	developed penetration limiters sooner than they		
17	Bard could have electropolished its retrievable	17	ultimately did. And they could have redesigned the		
18	filters before it did so in the Eclipse, you're not	18	filter configuration to try and find a better a		
19	going to give that opinion, you defer to	19	better combination of of of phenomena that		
20	Dr. Richie?	20	would improve the behavior of the filter in terms		
21	A Well, I	21	of the risks involved.		
22	MR. O'CONNOR: Form and foundation.	22	Q All right. So let's talk about caudal		
23	THE WITNESS: I'll defer to his opinion in	23	anchors and limiters. On what do you base your		
24	terms of the wires, but a point I would like to	24	opinion that Bard could have added caudal anchors		
25	make is that they could have switched to using tube	25	and limiters earlier than it did?		
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1	materials sooner, and they could have made the	1	A Well, the the reason is that they		
2	material out of tube material which they could	2	eventually did put caudal anchors on the filters,		
3	which they could have electropolished at the stage	3	and so my point is simply that they could have		
4	of of making the filters from tube material	4	started to consider that possibility sooner than		
5	rather than wires.	5	they they did, once they realized that caudal		
6	BY MS. DALY:	6	migration was contributing to tilt and tilt was		
7	Q I'm sorry, I'm missing what that word is.	7	contributing to other failures that the filter was		
8	What materials?	8	experiencing.		
9	A Oh, so	9	Q Okay. Do you know of any other IVC filter		
10	Q You said troop?	10	manufacturer who incorporated anchors or limiters		
11	A Tube.	11	earlier than Bard did?		
12	Q Tube materials.	12	MR. O'CONNOR: Form and foundation.		
13	A Tube, yeah.	13	THE WITNESS: Not to my knowledge.		
14	Q Got it.	14	BY MS. DALY:		
15	A T-u-b-e.	15	Q Okay. Do you know any do you know in		
16	Q Okay. Do you know of any manufacturer	16	any in-depth way what the process was internally in		
17	that was using tube materials to make IVC filters	17	Bard to develop these anchors and limiters?		
18	before the time that Bard came out with the	18	MR. O'CONNOR: Form.		
19	electropolished Eclipse?	19	THE WITNESS: I've read some of the		
20	A No.	20	documents that describe activities that were		
21	Q Do you have any papers you can cite me to	21	involved, but I I wouldn't say that I know in		
22	that that that one could electropolish wire	22	detail what the processes were that were involved		
23	adequately to have it improve any characteristic of	23	in developing those caudal anchors.		
24	an IVC filter before Bard did so in the Eclipse?	24	BY MS. DALY:		
25	MR. O'CONNOR: Form.	25	Q Do you know do you know of design		

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1	efforts that Bard made to add these anchors and	1	BY MS. DALY:
2	limiters that were unsuccessful initially and more	2	Q Uh-huh.
3	changes had to be made?	3	A And in other activities, which I cannot
4	MR. O'CONNOR: Form.	4	talk about, I've made similar comparisons among
5	THE WITNESS: I do know that some of the	5	filters.
6	designs of the caudal anchors that they	6	Q But you've said you're not going to rely
7	investigated did not work as well as others.	7	in this case on the comparisons you made in the
8	BY MS. DALY:	8	cases you can't talk about, right?
9	Q The other thing you talked about was that	9	A That's correct.
10	Bard could have redesigned the configuration of its	10	Q All right. So we'll set that aside for a
11	filters. It was a little vague to me. What do you	11	moment. But you you have developed no prototype
12	mean by that?	12	making changes to any of Bard's filters that you
13	A Well, I mean the the shape of the	13	think would perform better, correct?
14	limbs, the dimension of the limbs, in other words	14	MR. O'CONNOR: Form.
15	their their diameter, they could have considered	15	THE WITNESS: No, I've I've developed
16	different numbers of limbs, they could even have	16	no prototype to attempt to to achieve that
17	considered moving to a different material. So	17	objective.
18	there's a fairly large number of design choices	18	BY MS. DALY:
19	that could have been considered, and they could	19	Q And of course since you don't have a
20	well have come up with a combination of features in	20	prototype for that, you've not bench tested such a
21	the design that gave them a better combination	21	prototype to see how it would perform either, true?
22	of of phenomena in terms of how the filter	22	A That's correct.
23	behaved.	23	Q Okay.
24	Q Do you know are you aware of any steps	24	MR. O'CONNOR: Belated objection to the
25	that Bard took along the way from Recovery to	25	form of the question.
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1	Denali to look specifically at shapes, diameters of	1	BY MS. DALY:
2	limbs, numbers of limbs, new materials?	2	Q You talk about the changes to the G2X cap,
3	A Well, when they went from the Recovery to	3	and I want to know what your opinion is on the
4	the G2, they changed the shapes and the lengths	4	chamfer design in the G2X compared to the G2.
5	of of the limbs. When they went to the G2X,	5	MR. O'CONNOR: You can refer to your
6	they made some changes to the details of the cap	6	report, too, it's in there.
7	shape. And then of course the next big change -	7	BY MS. DALY:
8	adding caudal anchors and electropolishing were	8	Q Sure.
9	changes, but the next big change was moving to the	9	A In my opinion, the chamfer was changed
10	Denali where they use a tube instead of wires to	10	very little in going from the G2 to the G2X, and
11	design the the filter. But I'm not aware of	11	the reason is that although the cap was bead
12	whether they considered other changes such as	12	blasted, the chamfer area was masked during the
13	changing the number of limbs or moving to a	13	bead blasting and as a consequence of that, the
14	different material.	14	bead blasting would not have broken the sharp
15	Q Have you done any work to to look at	15	edges, which are the the problem that is
16	combinations of things like type of material,	16	associated with the chamfer. And this is contrary
17	diameter, shapes of limbs, numbers of limbs, that	17	to Dr. Fasching's claim that the bead blasting
18	you think would cause an IVC filter to perform	18	would have softened that particular sharp edge.
19	better?	19	The next point is that after the bead
20	A Well, in	20	blasting, there was a process of tumbling the cap
21	MR. O'CONNOR: Object to the form of the	21	in a bed of ceramic particles, and that would have
22	question.	22	removed some material by a process of pol
23	THE WITNESS: In this case, I've done a	23	essentially polishing, mechanical polishing, but in
24	comparison of the of the Recovery through Denali	24	my assessment it would not have removed a great
25	line of filters with the Simon nitinol filter.	25	deal of material and, therefore, would not have

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I	changed the shape of the chamfer very much.	1	radius of curvature, so if you don't change the
2	And as information that's consistent with	2	radius of the curvature very much, you're not going
3	that, we can look at Figure Figure 187 in	3	to change the strain concentration very much.
4	Dr. Fasching's report, which the report dated May	4	Q What's the largest curvature that you've
5	11 of 2017, where it can be seen that there are two	5	looked at to see how that would impact strain?
6	rounded edges at the bottom of the cap; one of them	6	A You mean what's the largest curvature I've
7	is very gradual, which is the one on the outside,	7	considered?
8	and my assessment is that that edge was broken by	8	Q Yeah. I thought you said that you looked
9	the bead blasting; whereas the one on the inside of	9	at a range and there was a large one that you
10	the cap adjacent to the limb you can see is much	10	looked at.
11	sharper in the sense that the radius of curvature	11	A Well, infinity would be the answer, which
12	is much smaller than the other curved surface.	12	of course is not
13	And I did an estimate of the radius of	13	Q Well
14	curvature and I found that the radius of curvature	14	A not a reasonable answer in the sense
15	for that chamfer is about 20 microns. Now, I would	15	that it's not practical for a filter.
16	defer to those who measure the the radius of	16	Q Did you actually model something on the
17	curvature directly in images on the electron	17	order of 40 microns, 50 microns, something like
18	microscope and so on, so I'm not going to say this	18	that?
19	is a definitive measure of the radius of curvature,	19	A No, what I modeled was a case where the
20	but it leaves me with the impression that the	20	chamfer is having no effect on raising the strains
21	radius of curvature is about 20 microns. And the	21	at the in the arms where the arms are in contact
22	radius of curvature that was measured by	22	with the chamfer.
23	Dr. Fasching on a Recovery filter quite some time	23	Q Okay.
24	ago was 15 microns.	24	A And that means that the radius of
25	And so it's my inference that there was	25	curvature is is just very large.
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1	not a big change to the radius of curvature of the	1	Q Do you know from any SEM work that either
2	chamfer in the processes that were used in the	2	Dr. Fasching has presented or Dr. Richie has
3	manufacture of the G2X. And that, therefore, the	3	presented whether the arms of G2Xs ever touch the
4	strain concentration which would be associated with	4	chamfer?
5	that chamfer was not reduced significantly,	5	A Did you say SEM work?
6	although if some material was removed, it would	6	Q Yeah.
7	have reduced the strain concentration to some	7	A Well, I have not seen that work
8	extent.	8	specifically, but as I look at these images it
9	Q Okay. So, first of all, let me start with	9	looks as if there is contact between the chamfer
10	that last thing first. You have not done any	10	and the arms. Although, again, I would not claim
11	specific modeling or FEA to determine what the	11	that that's a definitive interpretation of the
12	change in chamfer that you're willing to say	12	situation. But there are many images throughout
13	occurred to this 20 millimeters microns,	13	Dr. Fasching's report and Dr. Richie's reports
14	would what that impact would be on fracture	14	where you can see that there seems to be direct
15		15	contact between the chamfer and the the limb and
ı	resistance? You have not done any of that work	16	that that that contact seems to occur in several
16	specifically?	17	
17	A Well, I've I've considered the difference between a radius of curvature of 5	18	of the filters that they looked at.  Q How about G2Xs?
18			
19	microns and one in which, if you like, the radius	19	
20	of curvature is very large, but in between which	20	Q And just to be clear, are you aware that
21	spans the range from a radius of curvature of 5	21	they've seen very few G2Xs A That's
22	microns to ones which are much larger. But other	22	
23	than that, I've not done a specific calculation.	23	Q I think two.
24	But I should point out that the reduction	24	A Yeah, that's what I was going to comment
25	is proportional to the degree of change of the	25	on, that there's there's I'm not even sure,

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1	to my recollection, that there's a G2X looked at	1	Q Okay. So at the time that you wrote all
2	in in this report or in Dr. Richie's report	2	of these reports that we've marked as 2, 3 and 4,
3	other than the exemplar, so there's very little	3	you did not ask for those filters?
4	information to go on in that regard.	4	A That's right. But they they were
5	Q And did you see an exemplar G2X?	5	not seeing them was not relevant to my opinions
6	A I have an exemplar that I have in my	6	in the case.
7	possession.	7	Q So you're not going to rely on the
8	Q Okay. And have you done any bench testing	8	exemplars?
9	of that exemplar to see if you can cause wires to	9	A No. No.
10	touch the chamfer?	10	Q Okay. Have you talked to Dr. Richie about
11	A No.	11	the exemplars or his examination of the exemplars?
12	MR. O'CONNOR: Form and foundation.	12	A Well, I've looked at his report, but I've
13	THE WITNESS: No.	13	not talked directly with him about his examination
14	BY MS. DALY:	14	of them.
15	Q Were there any modifications to Bard's	15	Q Do you know if he has them?
16	retrievable filters starting with the G2 that did	16	A You mean sorry, my exemplars?
17	not go forward into the next model until the	17	Q Do you know if Dr. Richie has exemplars of
18	Denali, which you and I know is quite different?	18	them?
19	MR. O'CONNOR: Form and foundation.	19	MR. O'CONNOR: Form and foundation.
20	THE WITNESS: There - there may have been	20	THE WITNESS: I would need to look at
21	slight changes to the lengths of limbs, but other	21	Dr. Richie's report to see what exemplars
22	than that, I believe all of the modifications went	22	BY MS. DALY:
23	forward until the Meridian.	23	Q Well
24	MR. O'CONNOR: Are you done with the	24	A are included in that report.
25	Fasching report?	25	Q I deposed him June 9 and he complained he
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1	THE WITNESS: Yes.	1	didn't have them at that time. So you don't know?
2	MR. O'CONNOR: Keep your report in front	2	A I don't know.
3	of you and refer to it if you need to, please.	3	MR. O'CONNOR: Form.
4	BY MS. DALY:	4	BY MS. DALY:
5	Q Now, you have not examined an exemplar	5	Q Having looked at the Denali filter, you do
6	Meridian, correct?	6	see that there are some differences in that filter
7	A Yes, I have a Meridian in my possession.	7	than the previous ones, true?
8	Q Okay. When did you get that?	8	A Yes, that's correct.
9	A Oh, a week or two ago.	9	Q Okay. Is it your opinion that Bard has
10	Q Okay. Because I noticed it was not in	10	failed to reduce as far as reasonably practicable
11	your report at that time	11	by taking adequate protection measures risks of
12	A Right, Right,	12	tilt, perforation, fracture and migration in the
13	Q you did not have the Meridian. So from	13	Denali?
		4.4	A Yes.
14	what source did you get a Meridian?	14	
15	A I asked for it from the plaintiffs'	15	Q And what's the basis for that?
ı	A I asked for it from the plaintiffs' counsel.	15 16	Q And what's the basis for that? A Because you still see incidences of all of
15	A I asked for it from the plaintiffs' counsel.  Q And what about a Denali, do you have that?	15 16 17	Q And what's the basis for that? A Because you still see incidences of all of those phenomena in Denali filters.
15 16	A I asked for it from the plaintiffs' counsel.	15 16 17 18	Q And what's the basis for that? A Because you still see incidences of all of
15 16 17	A I asked for it from the plaintiffs' counsel.  Q And what about a Denali, do you have that?	15 16 17	Q And what's the basis for that? A Because you still see incidences of all of those phenomena in Denali filters. Q We'll we'll talk about that further later.
15 16 17 18	<ul> <li>A I asked for it from the plaintiffs' counsel.</li> <li>Q And what about a Denali, do you have that?</li> <li>A I have a Denali.</li> </ul>	15 16 17 18	Q And what's the basis for that?  A Because you still see incidences of all of those phenomena in Denali filters.  Q We'll we'll talk about that further
15 16 17 18 19	<ul> <li>A I asked for it from the plaintiffs' counsel.</li> <li>Q And what about a Denali, do you have that?</li> <li>A I have a Denali.</li> <li>Q When did you get that?</li> </ul>	15 16 17 18 19	Q And what's the basis for that? A Because you still see incidences of all of those phenomena in Denali filters. Q We'll we'll talk about that further later. You have not undertaken to compare reported rates or reported incidents, let's put it
15 16 17 18 19 20	<ul> <li>A I asked for it from the plaintiffs'</li> <li>counsel.</li> <li>Q And what about a Denali, do you have that?</li> <li>A I have a Denali.</li> <li>Q When did you get that?</li> <li>A About two weeks ago as well.</li> </ul>	15 16 17 18 19 20	Q And what's the basis for that? A Because you still see incidences of all of those phenomena in Denali filters. Q We'll we'll talk about that further later. You have not undertaken to compare
15 16 17 18 19 20 21	<ul> <li>A I asked for it from the plaintiffs'</li> <li>counsel.</li> <li>Q And what about a Denali, do you have that?</li> <li>A I have a Denali.</li> <li>Q When did you get that?</li> <li>A About two weeks ago as well.</li> <li>Q Do you know why you didn't get it before</li> </ul>	15 16 17 18 19 20 21	Q And what's the basis for that? A Because you still see incidences of all of those phenomena in Denali filters. Q We'll we'll talk about that further later. You have not undertaken to compare reported rates or reported incidents, let's put it
15 16 17 18 19 20 21 22	A I asked for it from the plaintiffs' counsel.  Q And what about a Denali, do you have that?  A I have a Denali.  Q When did you get that?  A About two weeks ago as well.  Q Do you know why you didn't get it before two weeks ago?	15 16 17 18 19 20 21 22 23 24	Q And what's the basis for that?  A Because you still see incidences of all of those phenomena in Denali filters.  Q We'll we'll talk about that further later.  You have not undertaken to compare reported rates or reported incidents, let's put it that way, reported numbers of incidents of any of
15 16 17 18 19 20 21 22 23	A I asked for it from the plaintiffs' counsel.  Q And what about a Denali, do you have that? A I have a Denali. Q When did you get that? A About two weeks ago as well. Q Do you know why you didn't get it before two weeks ago?  MR. O'CONNOR: Form.	15 16 17 18 19 20 21 22 23	Q And what's the basis for that?  A Because you still see incidences of all of those phenomena in Denali filters.  Q We'll we'll talk about that further later.  You have not undertaken to compare reported rates or reported incidents, let's put it that way, reported numbers of incidents of any of the complications you've identified in the various

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١.	Page 46		Page 48
1	Q Okay. Have you read the clinical trial	1	Q Okay. In paragraph 1 of the standards
2	that was done by authored by Dr. Stavropoulous	1	that you quoted back on the previous page, that
3	on the Denali filters that was published in 2016?	3	im that standard carries with it the
4	MR. O'CONNOR: Form and foundation.	4	understanding, does it not, that medical devices
5	THE WITNESS: Yes, I've read the paper and	1	carry risks?
6	the Bard report on that.	6	MR. O'CONNOR: Form. Foundation.
7	BY MS. DALY:	7	THE WITNESS: Can you specify the line
8	Q Okay. And do you recall that this Denali	8	where that is.
9	trial had 200 patients in it?  A I would need to see the document before I	9	BY MS. DALY:
10 11	could	10 11	Q Sure. Where it A The second to last line
12	Q Sure.	12	A The second to last line Q Yeah.
13	A answer that question.	13	- 100
14	Q We're going to mark this 12.	14	A it says it says "Provided that any risk which may be associated with their use
15	(Whereupon, Deposition Exhibit 12 was	15	
16	marked for identification by the Court	1	constitute acceptable risks"
17	Reporter.)	16 17	Q Right.  A "when weighed against the benefits."
18	BY MS. DALY:	18	So yes.
19	Q And my question for you is: Do you see it	19	Q Okay. So there is not in these GHTF
20	was 200 patients and it went for about a period of	20	standards that you've quoted any standard saying
21	two years?	21	that a medical device must have no risks associated
22	A Yes, there are 200 patients.	22	with it, true?
23	Q And do you know that they reported no	23	MR. O'CONNOR: Form.
24	fractures?	24	THE WITNESS: Not to my knowledge is there
25	A I see that in the abstract it says that	25	any such specification.
<u> </u>			Page 49
1	Page 47 they reported no fractures.	1	BY MS. DALY:
2	Q Okay. All right. Now, going back to your	2	Q And you're not aware of any standard, are
3	report, your report Exhibit 2, again we're back at	3	you, that says that implantable medical devices
4	page 5, Section 3.2.1, paragraph 3 there that goes	4	must be risk free?
5		ı	
	on to page 6 says	5	A I'm not aware of any such
l	on to page 6 says MR. O'CONNOR: Sorry, where are we looking	5	A I'm not aware of any such MR. O'CONNOR: Form.
6	MR. O'CONNOR: Sorry, where are we looking		MR. O'CONNOR: Form.
l		6	-
6 7	MR. O'CONNOR: Sorry, where are we looking at? I apologize.	6 7	MR. O'CONNOR: Form.  THE WITNESS: rule or regulation.
6 7 8	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's	6 7 8	MR. O'CONNOR: Form.  THE WITNESS: rule or regulation.  BY MS. DALY:
6 7 8 9	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's Exhibit 2.	6 7 8 9	MR. O'CONNOR: Form.  THE WITNESS: rule or regulation.  BY MS. DALY:  Q And are you aware of any implantable
6 7 8 9	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's Exhibit 2.  MR. O'CONNOR: You're going to page 6?	6 7 8 9	MR. O'CONNOR: Form.  THE WITNESS: rule or regulation.  BY MS. DALY:  Q And are you aware of any implantable medical device that is 100 percent risk free?
6 7 8 9 10	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.	6 7 8 9 10	MR. O'CONNOR: Form.  THE WITNESS: rule or regulation.  BY MS. DALY:  Q And are you aware of any implantable medical device that is 100 percent risk free?  MR. O'CONNOR: Form. Foundation.
6 7 8 9 10 11 12	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.	6 7 8 9 10 11	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk free? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough
6 7 8 9 10 11 12	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's  Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.  MS. DALY: To top.	6 7 8 9 10 11 12	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk free? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able
6 7 8 9 10 11 12 13	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's  Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.  MS. DALY: To top.  Q It says "Medical devices should achieve	6 7 8 9 10 11 12 13 14	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk free? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able to answer that question.
6 7 8 9 10 11 12 13 14	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's  Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.  MS. DALY: To top.  Q It says "Medical devices should achieve the performance intended by the manufacturer and be	6 7 8 9 10 11 12 13 14	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk free? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able to answer that question. BY MS. DALY:
6 7 8 9 10 11 12 13 14 15	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.  MS. DALY: To top.  Q It says "Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that during	6 7 8 9 10 11 12 13 14 15	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk free? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able to answer that question. BY MS. DALY: Q Okay. Now, going back to that paragraph
6 7 8 9 10 11 12 13 14 15 16	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's  Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.  MS. DALY: To top.  Q It says "Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that during normal condition of use they are suitable for their	6 7 8 9 10 11 12 13 14 15 16	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk free? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able to answer that question. BY MS. DALY: Q Okay. Now, going back to that paragraph 3, it it speaks in terms of the device being
6 7 8 9 10 11 12 13 14 15 16 17	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's  Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.  MS. DALY: To top.  Q It says "Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that during normal condition of use they are suitable for their intended purpose."	6 7 8 9 10 11 12 13 14 15 16 17	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk free? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able to answer that question. BY MS. DALY: Q Okay. Now, going back to that paragraph 3, it it speaks in terms of the device being managed being manufactured in such a way that
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's  Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.  MS. DALY: To top.  Q It says "Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that during normal condition of use they are suitable for their intended purpose."  Do you see that?  A I see that.  Q Okay. How do you interpret that statement	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk free? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able to answer that question. BY MS. DALY: Q Okay. Now, going back to that paragraph 3, it it speaks in terms of the device being managed being manufactured in such a way that during normal conditions of use. You see that language? A Yes.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. O'CONNOR: Sorry, where are we looking at? I apologize.  MS. DALY: His MDL report. It's  Exhibit 2.  MR. O'CONNOR: You're going to page 6?  MS. DALY: Yeah. Well, the bottom of 5.  MR. O'CONNOR: Thank you.  MS. DALY: To top.  Q It says "Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that during normal condition of use they are suitable for their intended purpose."  Do you see that?  A I see that.  Q Okay. How do you interpret that statement by that standard?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. O'CONNOR: Form. THE WITNESS: rule or regulation. BY MS. DALY: Q And are you aware of any implantable medical device that is 100 percent risk firee? MR. O'CONNOR: Form. Foundation. THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able to answer that question. BY MS. DALY: Q Okay. Now, going back to that paragraph 3, it it speaks in terms of the device being managed being manufactured in such a way that during normal conditions of use. You see that language? A Yes. Q What is normal conditions of use with

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	Page 50		Page 52
1	large fraction of the population of patients that	1	frank and honest with the FDA and did not fully
2	receive the device.	2	inform the FDA of deficiencies in the G2 filter."
3	Q Is there any definition that you're aware	3	Do you see that? It's at the very last
4	of in the standard that that's what they mean when	4	long sentence at the bottom of 10.
5	they say "during normal conditions of use"?	5	A Yes. I see that.
6	A I I I'm not aware of such specific	6	Q What's the basis for your opinion?
7	definition.	7	A The basis, I'm relying on Dr. Parisian for
8	Q Okay. Are you aware of any standard for	8	that opinion.
9	medical devices that says that normal condition of	9	Q Okay. You have not reviewed the materials
10	use is a wide range of uses or patient populations	10	that she has reviewed, for example, true?
11	or anything?	11	A I've not reviewed
12	MR. O'CONNOR: Form and foundation.	12	MR. O'CONNOR: Form.
13	THE WITNESS: I'm not aware of any	13	THE WITNESS: all of that material. I
14	specific regulation in that regard.	14	probably have seen some of it.
15	BY MS. DALY:	15	BY MS. DALY:
16	Q If you look at page 6, paragraph 6, where	16	Q And to your point a moment ago that you
17	you've quoted to the standard, it says "All known	17	are not giving opinions about FDA regulations, is
18	and foreseeable risk" "risks and any undesirable	18	it also fair to say that you are not giving
19	effects should be minimized and be acceptable when	19	opinions about what Bard's corporate behavior was
20	weighed against the benefits of the intended	20	vis-a-vis what was expected by the FDA?
21	performance of the medical devices during normal	21	A I'm
22	conditions of use."	22	MR. O'CONNOR: Form.
23	Do you see that?	23	THE WITNESS: I'm not offering such
24	A I see that.	24	opinion. Although may I go back and add to my
25	Q Are tilt, perforation, migration and	25	answer to your previous question
25		25	
١.	Page 51 fracture known and foreseeable risks of IVC		Page 53
1		I	BY MS. DALY:
2	filters?	2	Q Of course.
3	A Of many IVC filters, yes.  Q And are you aware that some of those	3	A which is that in a couple of
4	*	4	situations, I've identified information that Bard
5	events have undesirable effects on the patient and	5	gave to the FDA which was not correct, was not
6	some don't?	6	information that they should have provided as
7	MR. O'CONNOR: Form.	7	credible information; for example, the claim that
8	THE WITNESS: Well, I'm not a medical	8	the G2 was 12 times better than the Recovery in
9	expert so I can't really answer that question.	9	terms of its fatigue performance and, also, at the
10	BY MS. DALY:	10	same stage when the 510(k) was being undertaken for
11	Q Fair enough.	11	the G2, they represented calculations that they did
12	And similarly, as an as an engineer,	12	that were irrelevant to fatigue as being should
13	you're not qualified to give an opinion as to what	13	I stop?
14	the benefits are of any to any given patient of	14	MR. O'CONNOR: No. Finish your answer.
15	the use of an IVC filter, true?	15	THE WITNESS: Oh.
16	MR. O'CONNOR: Form.	16	So they they represented calculations
17	THE WITNESS: No, I would not do that. I	17	that were not done for fatigue situations which
18	would not offer such opinions on the benefits.	18	were in fact done to estimate the strains upon
19	BY MS. DALY:	19	implantation of the filter into the vena cava.
20	Q Okay. Are you giving any opinions in this	20	They represented those calculations as ones that
21	litigation that Bard complied with or failed to	21	could be used to understand or or represent
22	comply with any specific FDA regulations?	22	fatigue behavior of the filter, and they also
	4 3 7 7	100	4 14 = 1 14 1.1
23	A No, I'm not offering such opinions.	23	represented those calculations as being
23 24	A No, I'm not offering such opinions.  Q If you look at page 10 of the report	23 24	experimental tests that would validate the fatigue

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	Page 54		Page 56
1	So in my view, this information was at the	1	such opinion.
2	very least misleading.	2	BY MS. DALY:
3	MR. O'CONNOR: Okay, Hold on a second.	3	Q All right. Let's look at page 9 of that
4	Excuse me. What was ringing?	4	report where you start talking about the G2. I'm
5	THE COURT REPORTER: Sorry.	5	going to talk about arm strain issues first. Okay?
6	MR. O'CONNOR: Thank you.	6	A Okay.
7	BY MS. DALY:	7	Q What types of analyses did you perform to
8	Q So I appreciate that answer. My question	8	estimate strains on any of the Bard IVC filter
9	is: Are you going to take it the next step and	9	arms?
10	give the opinion that the intention of Bard was to	10	A I carried out calculations that were done
11	be not frank and not honest with the FDA?	11	by what is called Euler-Bernoulli beam theory, and
12	MR. O'CONNOR: Form.	12	I also carried out some finite element calculations
13	THE WITNESS: I I will not interpret	13	of some of the the filter limbs.
14	those actions in that way but, instead, rely on	14	Q And what were the principal assumptions
15	Dr. Parisian for the overall assessment of that	15	that you incorporated when you did your
16	situation.	16	calculations and/or FEAs about the Bard filter
17	BY MS. DALY:	17	arms?
18	Q All right. Thank you.	18	A In the F FEA?
19	And I guess one other question I have	19	Q Either remodeling or
20	there is: Do you have any idea what the FDA did	20	A Either
21	with the information that you've just described for	21	Q in the FEA.
22	us that Bard gave them about the G2? Do you know	22	A Yeah,
23	what they if they relied on it, if they asked	23	Q For example, I know that you assumed that
24	questions about it, if they rejected it? Do you	24	the vessel arm had perforated or endothelialized in
25	know?	25	the vessel?
	Page 55		Page 57
1	MR. O'CONNOR: Form.	1	A In some calculations I assumed that that
2	THE WITNESS: Well, I know that because of	2	was the case, yes.
3	some reports of contacts, reports with with the	3	Q Okay. What else?
4	FDA, that these points were well, the matter of	4	A And I assumed that it had the the
5	the 12 times better fatigue performance was was	5	arm had endothelialized to the wall of the vena
6	discussed with the FDA.	6	cava.
7	BY MS. DALY:	7	Q And when you say that, are you saying it's
8	Q Okay. Your report that we're on now, back	8	like setting rebar in concrete type of
9	at page 6, Section 3.2.2.2, it's entitled "FDA	9	endothelialization or that there's some allowable
10	Mandated Quality System Regulation Design	10	movement
11	Controls." And you just you cite to some of	11	A Well
12	those regs, correct?	12	Q considered in your calculations?
13	A Correct.	13	A I'm only saying that the tissue grows in
14	Q And then in 3.2 3.2.2.1 you talk about	14	such a way that it glues the arm to the wall of the
15	the class of devices that those the design	15	vena cava.
16	controls relate to, correct?	16	Q And that's what I'm saying. When you say
17	A Correct.	17	"glue," to what extent is the arm then
18	Q In citing this section or including this	18	unavailable unable to move, in your analysis?
19	section, are you providing any opinion that Bard	19	A Well, in my analysis it is constrained
20	failed to comply with FDA regulations as they	20	from experiencing rotating at the location where
21	relate to design controls, quality systems, design	21	it
22	validation, design output or verification that are	22	Q Okay.
23	listed on pages 6 and 7 of your report?	23	A is glued to the wall of the vena cava.
24	MR. O'CONNOR: Form.	24	Q All right. So do you also assume that
25	THE WITNESS: No, I'm not offering any	25	vessel motion is unaffected by the presence of the

	III I.O. Dulu I I O I III	_	<u> </u>
1	Page 58 filter in your calculations?	1	Page 60 BY MS. DALY:
2	A Yes.	2	Q What if others of the arms are not
3	Q Okay. And you also assume that the vessel	3	endothelialized to the point that they are
4	is stiff enough to prevent rotation at the tip of	4	basically glued, have you modeled anything like
5	the filter	5	that?
6	A Well	6	A I've not modeled that, no.
7	Q — is that right?	7	Q Okay. And the same question with the leg
8	A assume that the vessel and the	8	analysis that you did, you did not take it further
9	surrounding tissue and organs are stiff enough to	9	and look at what would what strains would be or
10	constrain that rotation, not just the wall of the	10	any of the legs of a filter if you assumed all six
11	vena cava itself.	11	legs, one of them in the glued position and the
12	Q It's the combination?	12	other ones in other conditions?
13	A It's the combination.	13	MR. O'CONNOR: Form.
14	Q And you assumed for purposes of some of	14	THE WITNESS: Yes, I have not done a
15	your arm calculations that there was linear elastic	15	calculation in which one of the legs is is under
16	material behavior?	16	different circumstances from the others.
17	A I assumed that that was the behavior	17	BY MS. DALY:
18	because that is the behavior that the arm will	18	Q Okay. One or more?
19	experience in the circumstances in certain of	19	A One or more, yes.
20	the circumstances involved.	20	Q Yeah. Okay.
21	Q And your analysis on arm strain there was	21	What structures in the body are sufficient
22	involving a single arm?	22	to contribute to the are sufficient to work with
23	A Correct.	23	the vena cava itself to prevent rotation at the
24	Q Did you do the same kind of analysis on a	24	tip?
25	leg, something that had the design dimensions or	25	A Well
25		25	· "
1	Page 59 characteristics of the leg?	1	Page 61 MR. O'CONNOR: Form.
2	A Well, I did some calculations of the	2	THE WITNESS: there's vertebra near the
3	behavior of a leg which is hit by a clot.	3	Vena cava.
4	Q Right. But not the kind of thing where	4	BY MS. DALY:
5	you're constraining the leg, gluing it?	5	Q Okay.
6	A Well, yes, the constraining of the leg was	6	A And
7	involved in that calculation as well.	7	Q What else?
8	Q Of the clot?	8	A there are some muscles which are quite
9	A Of the clot arriving at the leg and but	9	close to the vena cava, and so that it's it's
10	what I have not done is calculations where I look	10	feasible that they could enforce that they're
11	at the leg response to the expansion and	11	stiff enough to enforce enough constraint to limit
12	contraction of the vena cava.	12	the rotation of the of the limb of the vena
13	Q Okay. That's thank you.	13	cava.
14	So what you did not do was to take your	14	Q How about perforation
15	analysis of the arm that we've just talked about	15	A Of the limb of the filter. Sorry. Excuse
16	and expand that to be an analysis of all arms?	16	me.
17	MR, O'CONNOR: Form.	17	Q How about perforation of some other of
18	THE WITNESS: Well, it is in fact an	18	a strut to a duodenum?
19	analysis of all arms because the symmetry of the	19	A Well, I'm uncertain as to whether that
17	filter, as long as it remains in its designed	20	would have sufficient effect.
l .	inter, as long as it remains in its designed	21	
20	ahana the aummetry of the filter and the		O How about to a vessel?
20 21	shape, the symmetry of the filter and the		*
20 21 22	assumption that the vena cava itself is symmetric	22	A But can I
20 21 22 23	assumption that the vena cava itself is symmetric around the filter, ensures that all of the arms	22 23	A But can I Q Of course.
20 21 22	assumption that the vena cava itself is symmetric	22	A But can I

	MI ACO. Data I V C I III		
١.	Page 62		Page 64
1	A Which is that the duodenum does have some	1	Q Okay.
2	muscle around its perimeter, so there are some	2	A It's this paper here.
3	muscle structures associated with the duodenum.	3	Q All right. We're going to mark as 13 the
4	But I'm unsure whether that is going to be stiff	4	Laborda Kuo paper entitled "Respiratory-Induced
5	enough to have the effect that you're addressing.	5	Haemodynamic Changes: A Contributing Factor to IVC
6	Q Okay. What about a perforating strut to a	6	Filter Penetration," and its publication date is
7	vessel such as the aorta, an iliac artery, a renal	7	March 2015.
8	vein?	8	(Whereupon, Deposition Exhibit 13 was
9	A I don't have an assessment of the impact of of those organs.	9	marked for identification by the Court
10	Q Okay. What is the typical stiffness, if	10 11	Reporter.) BY MS. DALY:
12	you know, of either vertebra or muscle in the area	12	
13	around the vena cava?	13	Q Let me get that out of my pile and catch up with you.
14	A Well, Dr. Briant gives values for that, so	14	MR. O'CONNOR: Thank you.
15	it would be easiest to refer to his report to get	15	BY MS. DALY:
16	those stiffnesses.	16	Q All right. So tell me what in this paper
17	Q Do you have any criticisms of what he used	17	you rely on for what we were just talking about.
18	in that regard?	18	A Well, I I rely on the author's
19	A I don't have criticisms of the values that	19	measurements of the area reduction of the vena cava
20	he used in the for the modulii of the various	20	during Valsalva that they measured in a number of
21	materials.	21	patients, and I've forgotten how many patients, 101
22	MR. O'CONNOR: Is it warm in here?	22	patients that they measured this these this
23	(Brief discussion off the record.)	23	reduction in area in. And
24	BY MS. DALY:	24	O Where is that on the
25	Q So your assumption that the vessel	25	A It's it's summarized on in Table 2
			Three CC
1	Page 63 prevented rotation and is maintained in the same	1	Page 65 on page well, I'm not sure if your copy has page
2	motion as it did prior to filter implat	2	numbers but
3	implantation is an assumption you made in your	3	Q It does.
4	analysis in this case?	4	A Okay. 1195.
5	A Sorry, can you repeat the question.	5	Q Okay.
6	Q Yeah.	6	A And at the top you'll see that there's
7	You made an assumption that went into your	7	Table 2.
8	calculations in this case that the vessel was	8	Q Yes.
9	prevented from rotating under the condition that	9	A And what they did was they measured the
10	you modeled and it maintained the vessel	10	area reduction in the vena cava during Valsalva
11	maintained the same motion as it did prior to	11	Q Uh-huh.
12	filter implantation?	12	A and they did it in patients who had
13	A That's correct.	13	received either a Cook Celect or a Cook Tulip
14	Q Okay. Did you perform any calculations to	14	filter, and they found that where the filter was
15	justify those assumptions?	15	located, the area reduction of the vena cava was
16	A Well, I didn't perform any calculations	16	6 on average, 62.55 percent. And what they
17	but I've looked at some information that's in the	17	found is that elsewhere than where the filter is,
18	scientific literature and it's it's contained in	18	namely 3 centimeters above the filter and 3
19	one of the papers that I brought today. And if	19	centimeters below the filter, they found that the
20	I	20	area reduction was was 90 percent.
21	Q Yeah, you show me that	21	And so what that indicates is that the
22	A find that.	22	in the case of the Tulip and the the Celect
23	Q and I'll put a number on it.	23	filter, the filter is resisting the area reduction
24	Is it this one that I took away from you?	24	of the vena cava but only to the extent of making
25	A No, it's not that one. No.	25	the area reduction about two-thirds of the area

		T	
1	Page 66 reduction when the filter is not present. Now,	1	Page 68  A Yes, all patients was perforating
2	there's other information which is I need to	2	Q Perforating or not perforating
3	identify it, but I think if you go to page 1194	3	A Yes. Correct.
4	Q Okay.	4	Q Okay. After from the Valsalva event,
5	A and the right-hand column under the	5	for these Celect and Tulip filters, there was the
6	Results section.	6	filter resisting putting resistance up to the
7	Q Uh-huh.	7	reduction?
8	A And if you go to the one, two, three,	8	A Correct.
9	four, five the fifth paragraph which starts "In	9	Q Okay. Of two-thirds?
10	four patients with major filter penetration," you	10	A Well
11	see that in it's actually in 23 patients because	11	Q Approximately 60-some percent?
12	there were four with major penetration and 19 with	1	A Essentially, the area reduction was
13	minor penetration.	13	two-thirds of what it would be without the filter,
14	Q Uh-huh.	14	so, in other words, whereas when the filter was not
15	A And, therefore, at least 23 patients they	15	there, the area went down to about 11 percent of
16	found that the area reduction of the vena cava was	16	its original area. With the filter's present, on
17	71.93 percent on average.	17	average it went down to 37 percent or thereabouts.
18	And I interpret this to be the worst case	18	Q Meaning that in Valsalva there's less of a
19	in the sense that of the patients who had filters,	19	contraction/expansion
20	the ones who had penetrated filters were	20	A There's
21	experiencing the greatest reduction at the filter	21	Q with the filter in place?
22	of the area of the vena cava, and what this means	22	A That's correct, yes.
23	is that the area of the vena cava after Valsalva or	23	Q All right. So take me back to 11 the
24	as a consequence of Valsalva is about 28 percent of	24	page before that, 1194, so I understand what you're
25	its area before the Valsalva event takes place. So	25	saying there. So then they looked at 23 patients
	Page 67		Page 69
1	it's a very big reduction in the area of the	1	who had penetration, and do we know what
2	cross-section of the vena cava even although the	2	they're saying what they mean when they're
3	filter is present.	3	saying they say "Four patients had major filter
4	Q And what does that mean with respect to	4	penetration and nine had minor filter penetration"?
5	strains on the filter?	5	Do we know what their
6	A I didn't estimate the level of strains in	6	
		٠,	A I don't know what their definition of
7	the filter, and I can come to that in in a	7	Q Okay.
8	second when I go through my summary of the	7 8	Q Okay. A "major" and "minor" is. My only my
8 9	second when I go through my summary of the situation, because I would like to present that	7 8 9	Q Okay.  A "major" and "minor" is. My only my only reason for identifying that is that it was a
8 9 10	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard	7 8 9 10	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a
8 9 10 11	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.	7 8 9 10 11	Q Okay.  A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction
8 9 10 11 12	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your	7 8 9 10 11 12	Q Okay.  A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole.
8 9 10 11 12 13	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a	7 8 9 10 11 12 13	Q Okay.  A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole.  Q Okay. So with the penetrating ones,
8 9 10 11 12 13 14	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect	7 8 9 10 11 12 13 14	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really
8 9 10 11 12 13 14 15	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area	7 8 9 10 11 12 13 14 15	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know.
8 9 10 11 12 13 14 15	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.	7 8 9 10 11 12 13 14 15	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right.
8 9 10 11 12 13 14 15 16	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.  Q Okay. So the reduction of the area is	7 8 9 10 11 12 13 14 15 16 17	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right. Q With the penetrating ones in the Celect
8 9 10 11 12 13 14 15 16 17	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.  Q Okay. So the reduction of the area is connected to the Valsalva?	7 8 9 10 11 12 13 14 15 16 17 18	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right. Q With the penetrating ones in the Celect and Tulip filters, in Valsalva there was also a
8 9 10 11 12 13 14 15 16 17 18	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.  Q Okay. So the reduction of the area is connected to the Valsalva?  A Yes.	7 8 9 10 11 12 13 14 15 16 17 18	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right. Q With the penetrating ones in the Celect and Tulip filters, in Valsalva there was also a limitation to the contraction and expansion that
8 9 10 11 12 13 14 15 16 17 18 19 20	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.  Q Okay. So the reduction of the area is connected to the Valsalva?  A Yes.  Q Okay. And this study shows that in Celect	7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right. Q With the penetrating ones in the Celect and Tulip filters, in Valsalva there was also a limitation to the contraction and expansion that was seen when filters were in place?
8 9 10 11 12 13 14 15 16 17 18 19 20 21	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.  Q Okay. So the reduction of the area is connected to the Valsalva?  A Yes.  Q Okay. And this study shows that in Celect and Tulip filters, that with with no perforation	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right. Q With the penetrating ones in the Celect and Tulip filters, in Valsalva there was also a limitation to the contraction and expansion that was seen when filters were in place? A That's correct.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.  Q Okay. So the reduction of the area is connected to the Valsalva?  A Yes.  Q Okay. And this study shows that in Celect and Tulip filters, that with with no perforation being taken into consideration, let's look back on	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right. Q With the penetrating ones in the Celect and Tulip filters, in Valsalva there was also a limitation to the contraction and expansion that was seen when filters were in place? A That's correct. Q All right.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.  Q Okay. So the reduction of the area is connected to the Valsalva?  A Yes.  Q Okay. And this study shows that in Celect and Tulip filters, that with with no perforation being taken into consideration, let's look back on 1195	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right. Q With the penetrating ones in the Celect and Tulip filters, in Valsalva there was also a limitation to the contraction and expansion that was seen when filters were in place? A That's correct. Q All right. A So now instead of reducing to 10 percent
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	second when I go through my summary of the situation, because I would like to present that information specifically in terms of of the Bard filter rather than the Cook filter.  But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.  Q Okay. So the reduction of the area is connected to the Valsalva?  A Yes.  Q Okay. And this study shows that in Celect and Tulip filters, that with with no perforation being taken into consideration, let's look back on	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Okay. A "major" and "minor" is. My only my only reason for identifying that is that it was a subset of the of of the cohort and it has a worst worst case in terms of how much reduction was involved compared to the cohort as a whole. Q Okay. So with the penetrating ones, forget how much they are because we don't really know. A Right. Q With the penetrating ones in the Celect and Tulip filters, in Valsalva there was also a limitation to the contraction and expansion that was seen when filters were in place? A That's correct. Q All right.

1 2 3 4 5 6 7	Page 70 Q Okay. Now, look at the last sentence in that paragraph that you pointed out that begins "In four patients." The last sentence says "Penetration was not significantly related to	1 2 3	Page 72 stiffer than the Bard filters, which means they would resist the reduction in area more than the Bard filter. So I deduce from that that the
2 3 4 5 6	that paragraph that you pointed out that begins "In four patients." The last sentence says	2	would resist the reduction in area more than the
3 4 5 6	four patients." The last sentence says	1	
4 5 6	- · · · · · · · · · · · · · · · · · · ·	3	Bard filter So I deduce from that that the
5 6	"Penetration was not significantly related to		
6		4	reduction in area when the Bard filter is present
1	venous pressure increase."	5	in these 23 patients that have the larger area
7	Do you know what they meant by that?	6	reduction would see an even bigger reduction in
1	A Well, in the paper, they measure the	7	area than was observed when the Celect or Tulip
8	increase of the pressure during Valsalva, and I'm	8	filter was present.
9	not exactly sure what they mean but they they	9	And it's my assessment that the area
10	obviously found that the venous pressure didn't	10	reduction could even approach the 90 percent that
11	matter to the penetration which was involved	11	was observed in the absence of the filter because
12	which they observed in the in the cohort. But	12	of that difference in stiffness of the of the
13	I'm not	13	filters involved.
14	Q Yeah.	14	Q Meaning with the Bard filters, you would
15	A I should say I'm not exactly sure what	15	expect a present Bard filter to put up some
16	they mean by this.	16	resistance to the reduction that Valsalva is
17	Q The way I read it is that the venous	17	causing?
18	pressures that they read on all patients were	18	A Correct.
19	were about the same whether you had penetration or	19	MR. O'CONNOR: Form.
20	you didn't.	20	BY MS. DALY:
21	A I guess so, yes.	21	Q But your deduction is that it could be as
22	Q Okay.	22	little as 90 percent?
23	A I'm not sure if that's what it means, but	23	A Well, no, that's not quite what I said.
24	that's a reasonable interpretation.	24	Q Okay.
25	Q And what we also don't know from this	25	A What I said is that the resistance could
	Page 71		Page 73
1	paragraph is what the differences were in the	1	be so small that the reduction in area would be
2	reduction of the cross what do we call that?	2	almost 90 percent, very similar to what is observed
3	A Cross-sectional.	3	when the filter is not present.
4	Q Cross-sectional, we don't know what the	4	Q Okay. So what have you done insofar as
5	cross-sectional reduction was keyed to whether you	5	modeling or FEAs to confirm your deduction that the
6	had multiple perforations at 5 millimeters or you	6	resistance with the Bard filters in place could be
7	had two perforations at 3 millimeters, there's no	7	very small?
8	information?	8	A I didn't do finite element analysis, I
9	MR. O'CONNOR: Form.	9	just made that estimate that the stiffness is
10	THE WITNESS: Well, there's no information	10	perhaps five times greater in the case of the
11	on that, but that's not relevant to my assessment	11	Celect filter compared to the Bard filter and that,
	of of this information.	12	therefore, when the Bard filter is there, the
	BY MS. DALY:	13	reduction in area is going to be more than when the
14	Q Okay. So why is this information	14	Celect filter is there.
	important to you as you relate it to the Bard	15	Q And where are your calculations that show
	filters?	16	my calculations and what assumptions I used for
17	A Okay. So Celect filters and Tulip filters	17	Celect, Tulip, and what assumptions I used for Bard
1	are significantly stiffer than Bard filters.	18	in that regard?
	Perhaps the limb of a Celect filter is perhaps 10	19	A I didn't
	times the stiffness of of a Bard filter, and	20	MR. O'CONNOR: Form.
	·	21	THE WITNESS: I didn't bring them with me.
20	that's only based on public information that is		
20 21	that's only based on public information that is available by measuring the diameter of a filter and		O Do you have that?
20 21 22	available by measuring the diameter of a filter and	22	Q Do you have that? A Yes.
20 21 22 23	" =		<ul><li>Q Do you have that?</li><li>A Yes.</li><li>Q Can you send it to Mark so he can send it</li></ul>

	in Re: Bard IVC Fill	VI3 1	Toddolis Didoliity
	Page 74		Page 76
1	A Yes, I can do that.	1	MR. O'CONNOR: I think he's covered this
2	Q All right.	2	area in his rebuttal report.
3	A But I need to continue with my	3	MS. DALY: Well, we'll argue about that
4	information.	4	later.
5	Q Oh, yeah, keep going.	5	THE VIDEOGRAPHER: Excuse me, Counsel,
6	A So now if I could have a copy of	6	your microphone, when you get a chance. Sorry to
7	Dr. Briant's report. Do you have one available?	7	interrupt.
8	Q Hmmm. I don't know that I do.	8	THE WITNESS: So
9	A Well, I can do it without reference to his	9	BY MS. DALY:
10	report.	10	Q So take me to a page, would be great.
11	MR. O'CONNOR: Let's see if you have the	11	A So yes.
12	report.	12	Q All right.
13	MS. DALY: I do not.	13	A In this fashion, page 33.
14	Q You mean his general MDL one? I do not	14	Q Okay.
15	have	15	A Just before Section 4.3.2.
16	A Yes.	16	Q All right.
17	Q I do not have that with me.	17	A And you see that these are there's a
18	A Okay. So he does calculations in which he	18	Figure 23
19	has his model of the physiology surrounding the	19	Q Okay.
20	vena cava.	20	A in which modeling of the Valsalva
21	Q Uh-huh.	21	processes is is undertaken.
22	A And he imposes displacement, I'm referring	22	Q Okay.
23	specifically to Configuration 3 where he is	23	A And Dr. Briant presents his results, which
24	modeling Valsalva	24	are in blue, and my results, which are in red,
25	Q Okay.	25	where I assume that the filter does not restrict
	Page 75		Page 77
1	MR. O'CONNOR: Here, I got a copy of the	1	the contraction of the vena cava at all.
2	report.	2	Q Uh-huh.
3	MS. DALY: Okay. Good. Let's let him	3	A And you observe in the case where the
4	look at that. Give us a page.	4	reduction the nominal reduction is 50 percent,
5	MR. O'CONNOR: Which report are you	5	that my results are about 10 times larger than his.
6	looking at? Which report are you referring to?	6	Now, there's an adjustment that should be made
7	THE WITNESS: It's I'd need to look at	7	because, as you've referred to, I assume no
8	it before I can say which one it is.	8	rotation of the of the arm where it intersects
وا	BY MS. DALY:	9	the vena cava wall.
10	Q And while he's looking for that, what	10	Q Uh-huh.
11	you're about to say about Briant's report is not in	11	A Which will essentially double the strains
12	your rebuttal report, this is new?	12	that I compute. So if if we take that out of
13	A This is new that's correct, it's new.	13	the picture, then we have strains in my case which
14	Q Okay.	14	are about five times the strains that that he
15	MS. DALY: I'm not saying that's okay, to	15	calculates.
16	your lawyer	16	Q Okay.
17	THE WITNESS: No, but	17	A Now, what that indicates is that the
18	MS. DALY: Hold on one second.	18	deflection of the arm is about in his case, is
19	Mark, I'm not saying it's not necessarily	19	about one-fifth of the deflection of the arm in my
20	true okay, we're going to talk about it, but I	20	case, which means that the reduction in area of the
21	think he was supposed to put everything in his	21	vena cava where the filter is is present would
22	rebuttal.	22	only be about one-fifth of the reduction in area of
23	MR. O'CONNOR: Well, I think he's	23	the vena cava in the absence of the filter.
24	covered	23 24	Q Okay.
25	MS. DALY: Go ahead.	2 <del>4</del> 25	A But as we've I've already pointed out,
23	MD. DALT. OV alleau.	23	A Dut as we ve I ve already pointed out,

	Page 78	1	Page 80
1	that in the experimental data, the reduction in	1	Q All right.
2	area should be much more like three-quarters or	2	A When you say "a test," you mean
3	even 80 percent where the filter is present	3	Q Like a bench test.
4	compared to where the filter is not present.	4	A Not in a bench test, no.
5	Q And how would that change his blue versus	5	O And
6	your red?	6	A Or even
7	A Well, his it would bring his blue up to	7	Q do we even know how we would do that?
8	halfway up my red because I'm discounting the	8	A in a clinical test.
9	constraint on rotation	وا	O How would we do that in a bench test?
10	O Okay.	10	A I think I know how to do it but I don't
11	A when making that comparison, to try and	111	Q You haven't developed one yet?
12	make it as a direct comparison as possible.	12	A Yes. Exactly.
13	Q And are you in telling me this now, are	13	Q Okay.
14	you taking into consideration what you've just	14	MR. O'CONNOR: But were you done with your
15	previously told me, that you think that the Bard	15	answer? You were saying did you do something
16	filter in place has a small resistance, somewhere	16	else? I didn't follow your answer.
17	on the order of 10 percent?	17	THE WITNESS: Sorry, which answer are
18	A Yes.	18	you -
19	MR. O'CONNOR: Form.	19	BY MS. DALY:
20	THE WITNESS: When I said that the results	20	Q I thought you answered to me what
21	would come up to halfway along my red results, that	21	THE WITNESS: Which answer are you
22	assumes that the Bard filter has no resistance	22	referring to?
23	relative to contraction of the vena cava. If I	23	MR. O'CONNOR: Just continue.
24	take the other result, which is that its resistance	24	THE WITNESS: Okay.
25	would reduce the area reduction to two-thirds, that	25	BY MS, DALY:
	Page 79		Page 81
I	would still bring you up to a third of of the	1	Q Okay. Is there anything else you wanted
2	way up my red mark; in other words, deflections and	2	to say from Dr. Briant's report about the topic
3	strains which are much bigger than Dr. Briant has	3	we're on?
4	calculated.	4	A About the which?
5	BY MS. DALY:	5	Q Topic that we're on right now?
6	Q Okay. And then what you have not done	6	A Well, all I want to say is that this
7	with what you just discussed with me, you haven't	7	deduction tells me that my assumptions are much
8	done an FEA specific to that issue, true?	8	closer to being relevant to what really happens in
9	A I haven't done FEA, but I've done all the	9	the vena cava, both during normal breathing and
10	Bernoulli calculations which are specific to that	10	during Valsalva, than the assumptions that
11	situation and which relax the rotation constraint.	11	Dr. Briant has made. And it's my deduction from
12	And that's that is mentioned in the report where	12	that that what he should have done to make it more
13	I comment that the rotation constraint	13	realistic would have been to impose the
14	approximately doubles the strains which are	14	displacement constraints much closer to the vena
15	involved.	15	cava than he actually did; in other words, instead
16	Q And are you aware of any medical	16	of having the physiological model of the
1 10		I	surroundings go out to
17	literature that looks at Bard filters for its	17	1
	literature that looks at Bard filters for its impact on resistance to expansion as was done by	17 18	MR. O'CONNOR: That's mine.
17		l	I
17 18	impact on resistance to expansion as was done by	18	MR. O'CONNOR: That's mine.
17 18 19	impact on resistance to expansion as was done by Laborda with the Celect and Tulip filter?	18 19	MR. O'CONNOR: That's mine. THE WITNESS: Oh, sorry.
17 18 19 20	impact on resistance to expansion as was done by Laborda with the Celect and Tulip filter?  A I haven't seen any such data or papers.	18 19 20	MR. O'CONNOR: That's mine. THE WITNESS: Oh, sorry. MR. O'CONNOR: That has my notes on it.
17 18 19 20 21	impact on resistance to expansion as was done by Laborda with the Celect and Tulip filter?  A I haven't seen any such data or papers.  Q And you haven't tried to recreate that in	18 19 20 21	MR. O'CONNOR: That's mine. THE WITNESS: Oh, sorry. MR. O'CONNOR: That has my notes on it. MS. DALY: That's all right. He can talk
17 18 19 20 21 22	impact on resistance to expansion as was done by Laborda with the Celect and Tulip filter?  A I haven't seen any such data or papers.  Q And you haven't tried to recreate that in a test yourself?	18 19 20 21 22	MR. O'CONNOR: That's mine. THE WITNESS: Oh, sorry. MR. O'CONNOR: That has my notes on it. MS. DALY: That's all right. He can talk from it, I won't look at your notes.

	III Ke. Daid IVC Fill	.0131	Toddots Eldonity
١.	Page 82		Page 84
1	impose the displacement constraints closer to the	1	nitinol.
2	vena cava. I'm not sure where, but closer than the	2	Q Have you submitted fatigue strain analyses
3	1 inch that he assumed in his calculation.	3	for any medical device submission or consulting
4	BY MS. DALY:	4	work where you only did analyses that included
5	Q But you agree that there has been no bench	5	linear elastic calculations?
6	testing done by either you or Dr. Briant to verify	6	A Well, the yes, in the sense that the
7	what you've done with modeling, true?	7	linear elastic calculations were presented in
8	A Could you repeat the question.	8	parallel with calculations that were done using
9	Q There has been no bench testing done under	1	nonlinear nitinol constitutive laws as well.
10	any protocol by either you or Dr. Briant to try to	10	Q At page 53 of your report, it's the last
11	verify what you modeled?	11	paragraph I wanted to ask you about, it says "The
12	MR. O'CONNOR: Form.	12	analysis just described requires follow-up by more
13	THE WITNESS: You mean	13	detailed exploration by FEA as it shows that cyclic
14	BY MS. DALY:	14	strains are potentially dangerously high."
15	Q On this issue. On this issue	15	Do you see that?
16	A this specific issue?	16	A I see that.
17	Q Yes, sir.	17	Q And what does that relate to? Which
18	A No, I agree. No.	18	which which of the analyses is that relating to?
19	Q Okay. And you are not aware of any	19	A Well, the analyses that it relates to
20	clinical work that's been done looking at a Bard	20	would be those strain ranges in my calculations
21	filter in a patient in Valsalva to try to look at	21	that fall outside of the linear elastic range
22	this to try to gain the same data that Laborda	22	because that requires a nonlinear analysis to carry
23	got in the Celect/Tulip study?	23	it out. But I should say that where those strain
24	A I'm not aware of any such paper or data.	24	levels are that high, then you're already looking
25	Q Okay.	25	at worrisome levels of strain.
	Page 83		Page 85
1	MR. O'CONNOR: Are you done with that?	1	Q And have you done any more detailed
2	THE WITNESS: May I just add one thing,	2	exploration by FEA of that issue?
3	which is and perhaps I wasn't finished with the	3	A Not of that issue, no.
4	answer that was which is that since the boundary	4	Q Okay. You state there that the cyclic
5	conditions I used are much closer to being	5	strains are potentially dangerously high. That was
6	realistic in my opinion, it means that the strain	6	your term?
7	amplitudes that I computed are more are more	7	A Yes.
8	realistic in terms of representing what will happen	8	Q Does your analysis show what the potential
9	both during normal breathing and during Valsalva.	9	high strains are?
10	Although, I would say that there's still the	10	A Could you repeat that question and
11	question of the rotation which could be debated in	11	possibly clarify.
12	terms of what that will do to the strain levels	12	Q Yeah.
13	involved.	13	Does your analysis show what the potential
14	But I've assumed that as a worst case,	14	high strains are, the range of potential high
15	which is almays always my concern when I make	15	strains are, in that particular analysis where
16	the assumptions about how to do the calculations.	16	you're saying the cyclic strains are potentially
17	BY MS. DALY:	1 <b>7</b>	dangerously high?
18	Q Do you retain do you routinely assume a	18	A Can you
19	linear elastic constitutive response for nitinol	19	Q Yeah, it's that same sentence at the
20	A I	20	bottom bottom paragraph of 53, first sentence.
21	Q in your analysis for companies during	21	You're talking about the analysis
22	device development relating to nitinol products?	22	A Okay. So
23	A Well, yes, when the response that is being	23	Q and you say more detailed exploration
24	investigated is in the linear elastic regime, I use	24	by FDE FEA should and then it says "as it
25	a linear elastic model for the behavior of the	25	shows that the cyclic strains are potentially

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	Page 86		Page 88
1	dangerously high." That's what I'm asking about.	1	that Dr. Briant obtained, adjusting for the
2	What does that mean?	2	different assumptions which went into the
3	A So is this question independent of whether	3	calculations, and I find that my results are always
4	FEA should be done?	4	consistent with his results in terms of the
5	Q Yes,	5	magnitude of the strains which are predicted.
6	A Is it simply	6	Q So let's go back to your report, page 9,
7	Q Yes. Yes.	7	and we were back on we were back on the G2
8	A Yes. Okay.	8	section.
9	So in the preceding pages, there are a	9	A Okay.
10	number of results that give you levels of strain at	10	Q And this initial discussion in paragraph
11	the place where the limb where the arm enters	11	1 I'm sorry, number the number 1, not
12	the cap and that is where, given my assumptions	12	paragraph 1, but go down to where you got
13	that the level of strains is highest, and some of	13	A Oh, yes.
14	those values are in excess of levels that Bard	14	Q the 1.
15	would identify as the fatigue limit of the	15	A Yes,
16	material.	16	Q And you're talking about the alternating
17	And, in addition, many of the results are	17	strain in the arm of the G2?
18	higher than the fatigue limit of similar materials,	18	A So we're talking about paragraph 2 or
19	and in those circumstances one would worry that	19	Section 2 of this?
20	when you're in a danger level because the	20	Q Yes, and I'm talking about the No. 1
21	material similarities and dissimilarities may mean	21	A Yes.
22	that this is a high enough level of strain to cause	22	Q that begins "The alternating strain in
23	fatigue failure of the material.	23	the arm." Okay. Is it your opinion that the
24	Q And that was really my question. Your	24	strain in the arm that you're discussing there
25	"dangerously" term goes to it might be approaching		could be a contributor to fracture or is that also
	Page 87	1	Page 89
1	its fatigue	1	relating to any of the other complications,
2	A Yes, so I	2	migration, perforation or tilt?
3	Q Its fatigue limit?	3	A Well, it's it's related to fracture.
4	A That so I can clarify precisely my	4	That's its relevance.
5	Q Okay.	5	Q Okay. In that same No. 1 section, you say
6	A answer, which is that some of these	6	that "the arm has fully perforated." What do you
7	results lie above the fatigue limit that Bard	7	mean by the term "fully perforated"?
8	identified	8	A I mean that the arms have gone through the
9	Q Got it.	9	vena cava to such an extent that the arms are in
10	A for their material.	10	their design shape, which is the shape they would
11	Q Good. Okay.	11	be in when the filter is simply sitting on the
12	A And can I make one more comment, which is	12	table in front of us.
13	that if that situation is modified by the strain	13	Q So it would how far they're out would
14	concentration, then the level of strains is even	14	depend on the diameter of the vena cava of the
15	higher, and that means that some of these other	15	person?
16	results which lie below the Bard fatigue limit	16	A That's correct.
17	might rise above the Bard fatigue limit because of	17	Q All right. With what frequency does a
18	the strain concentration.	18	full perforation like that occur in patients that
19	Q Okay. But again, with respect to those	19	have Bard filters?
20	things, there have been no separate FEAs done to	20	MR. O'CONNOR: Form and foundation.
21	verify?	21	THE WITNESS: I I don't know the answer
22	A Well, there's one FEA that we did which	22	to that.
23	confirms the strain levels which I computed by	23	BY MS. DALY:
1	Euler-Bernoulli beam analysis and I've compared the	24	Q You're aware of individuals either in the
24	CONTRACTOR OF THE PROPERTY OF		~ A VIOLO VI III WITH VIOLET VIOLET VIOLET III WILL

23 (Pages 86 - 89)

medical literature or in cases that you've seen on

25

strain levels that are in these tables with results

25

	In Re: Bard IVC File	_	
١.	Page 90	1	Page 92
	this litigation who experience no fracture but have	1	MR. O'CONNOR: When you get to a point,
2	perforations of different kinds, true?  A Yes. Correct.	2	can we take a break?
3		3	MS. DALY: Sure. I'm heading to page 11,
4	Q Tilts of different kinds?	4	We'll take a break.
5	A Correct.	5	MR. O'CONNOR: Oh, okay.
6	Q And even migrations of different kinds?	6	THE WITNESS: The break is now?
7	A Yes.	7	MS. DALY: Yes.
8	Q In that in that sentence, you make an	8	THE WITNESS: Okay.
9	assumption about the arm having endothelialized by	9	THE VIDEOGRAPHER: This is the end of
10	the tissue. We've just talked about what you mean	10	Media No. 1. We are going off the record at 10:52.
11	by that, correct?	11	(Recess taken.)
12	A Right, Right, Correct.	12	THE VIDEOGRAPHER: This is the beginning
13	Q All right. With what frequency does that	13	of Media No. 2. We are back on the record at
14	type of endothelialization, in effect gluing the	14	11:06.
15	arm as you modeled it, happen in patients who have	15	BY MS. DALY:
16	IVC filters?	16	Q Dr. McMeeking, I'm going to start on page
17	MR. O'CONNOR: Form and foundation.	17	11 of your report, please.
18	THE WITNESS: Well, I'm I'm not a full	18	A Okay.
19	expert on that issue, but it's my understanding	19	Q And what I wanted to talk about was at
20	that almost all of the filters endothelialize	20	this point in your report, you're talking about a
21	eventually to the wall of the vena cava.	21	model that you were using and that that involves
22	BY MS. DALY:	22	a filter arm fully perforating in this model?
23	Q To the extent that you modeled it?  A You mean to the extent that it would	23	A Can you draw me
24 25	constrain the rotation?	24 25	Q Yeah, I
2.5	·	25_	A Draw my attention to a specific line.
,	Page 91		Page 93
1	Q Yes.	1	Q Yeah, I'm just I'm about to talk about
2	A I don't know the answer to that question.	2	the Murphy paper and the Laborda paper.
3	Q Okay.  A But I should comment that it — it's not	3	A Okay.
4		4	Q It's at the top of 11.
5	so much whether the wall will directly constrain the rotation as that the interaction of the end of	5	A All right. Fine.
6		6	Q And so what I think is happening here is
7	the filter arm, the wall of the vena cava, and the	7	you're modeling the filter fully perforating and
8	material outside the vena cava, plus the motions	8	the endothelia endothelialized arm, correct?
l	which are being imposed on that system, will affect		A Correct. That's correct.
10	how the arm moves.	10	Q And then you're you're about to talk
11	Q Right. And there can be thousands, I	11	here or you do talk here about movement of greater
12	think Dr. Richie said millions, of permutations of	12	than 1 millimeter of the arm?
13	filter condition in a in people, fair?	13	A Yes.
14	A That's correct.	14	Q Okay. So let's talk about Murphy for a
15	MR. O'CONNOR: Form.	15	minute.
16	THE WITNESS: But my my assessment is		A Okay.  (Wharauman Danasition Exhibits 14 and 15)
17	always to find the worst-case condition that is	17	(Whereupon, Deposition Exhibits 14 and 15
18	likely to occur.	18	were marked for identification by the
19	BY MS. DALY:	19	Court Reporter.)
20	Q On any of the worst-case conditions that	20	BY MS. DALY:
21	you have considered in your analyses, with what	21	Q You cite to the Murphy study, and let me
22	frequency does that set of conditions occur in	22	go ahead and give you I'm going to talk about
23	patients with Bard filters?	23	Laborda too. I've marked as 14 the Murphy study,
24	MR. O'CONNOR: Form and foundation.	24	"Evaluation of Wall Motion and Dynamic Geometry,"
25	THE WITNESS: I don't know.	25	and as 15 the Laborda "Influence of breathing

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	III Ke. Daid IVC Fill		
	Page 94		Page 96
1	movements and Valsalva maneuver on vena cava	1	of the span of the vena cava in some cases was as
2	dynamics."	2	small as .6 millimeters and was in some cases as
3	A Okay.	3	big as 1.8 millimeters.
4	Q Okay. So the Murphy paper came out in	4	Q Did you use that information in any of
5	2008?	5	your analysis?
6	A Correct.	6	A Well, in some of it, yes.
7	Q Okay. And the Laborda paper that I just	7	Q And how did you use it?
8	handed you was published in 2 2014?	8	A I I took the 1.8 millimeter expansion
9	A That's correct.	9	and contraction of the diameter and I assumed that
10	Q Now, the Laborda paper that we just talked	10	that would take place on the span of the of
11	about a few moments ago that related to the Celect	l .	the the short span of the vena cava with having
12	and Tulip, when when did that paper come out?	12	the smallest span of all those that Murphy, et al.
13	A It was published in 2015.	13	looked at; namely, the the short span of the
14	Q Okay. Now, Murphy's study was of a small		vena cava that they looked at ranged from, well,
15	number of patients and he was looking at what?	15	the standard deviation, so it wasn't necessarily
16	A She and her colleagues were looking at the	16	the shortest span. The standard deviation took the
17	expansion and contraction of the vena cava during	17	diameter down to 10.2 millimeters.
1		18	I then assumed the 1.8 millimeter would
18	normal breathing in supine patients who had been		occur for that 10.2 millimeter diameter vena cava
19	anesthetized for yeah.	19	
20	Q Are you aware of any study similar to	20	as the worst case that was possible in the
21	Dr. Murphy's study prior to the time that she	21	combination of results that they obtained, and that
22	published that in 2008?	22	gave me an 18 percent reduction in the diameter of
23	A Well, there there are studies by	23	the vena cava. And I used that as a worst-case
24	various individuals, I can't name them, but there	24	possibility of what would happen during normal
25	were studies prior to that using various methods to	25	breathing in the in a patient's vena cava.
	Page 95		Page 97
1	try and establish the expansion and contraction of	1	Q Did you take into consideration, in using
2	the wall of the vena cava.	2	that number, what the presence of a filter might do
3	Q And was there any discussion in the Murphy	3	to restrict the change in the vena cava by
4	paper about any impact that an in situ IVC filter	4	respiration?
5	would have on expansion and contraction of the vena	5	A No, I didn't take that into consideration,
6	cava during respiration?	6	and for the reasons that we've just discussed. I
7	A I don't recall. I	7	don't think that is necessary in terms of getting
8	Q These were patients without IVC filters?	8	worst-case condition. Yes.
9	A That's correct, they had no filter.	9	Q And again, what we've already talked about
10	Q Okay. Do you know whether other doctors	10	is you've told me what you have done and what you
11	or scientists agree or have come to the same	11	haven't done to determine how much presence of a
12	conclusions that Murphy came to with this small	12	Bard filter will change the expansion of the vena
13	study?	13	cava whether under respiration or Valsalva?
14	A Well, I recall that prior to this study,	14	A That's correct, but but what I'm saying
15	there were different values for the expansion and	15	is that if you deduce what are the worst-case
16	contraction that one would see in the literature.	16	conditions, that the filter is not stiff enough to
17	Some of some of them smaller than the results in	17	resist the motion of the vena cava, and the
l		18	combination of data in the Murphy, et al. paper
18	Murphy, et al.	19	
19	Q Okay. And what did Murphy determine?		comes out in the way that I described it, then the
20	A They determined may I look at the	20	worst case is that even with the filter, the
21	paper?	21	contraction is 18 percent of the diameter.
22	Q Yes. Of course.	22	Q Have you done any testing of any kind or
23	A They determined that on the short axis of	23	seen any other clinical testing that looks at the

respiration impact in patients who do have a vena

24

25

cava filter present?

a vena cava which was approximately elliptical,

that the expansion and contraction of the diameter

24

	In Re: Bard IVC Fin		Toducts Elability
	Page 98		Page 100
1	A Well, there's the paper we discussed by	1	conditions to arise because tilting and
2	Laborda, et al. that has the study of the patients	2	perforation well, tilting is not in this
3	with Celect and Tulip filters.	3	assumption, but but perforation is progressive
4	Q But that's in Valsalva, right?	4	and can take some time to develop. It might be a
5	A That's in Valsalva.	5	matter of weeks or it might be a matter of of
6	Q I'm limiting it right now to just regular	6	of a number of years.
7	respiration.	7	Q And you don't know patient to patient how
8	A I haven't seen any studies I'm not	8	long that takes, true?
9	aware of any studies where there is a filter	9	A No, I don't.
10	present and this study the equivalent of this	10	Q And what degree of perforation are you
11	study has been carried out.	11	saying is necessary to start this clock ticking for
12	Q Do you know that Bard was aware of the	12	your analysis of failure in 5.5 to 111 hours?
13	Murphy study after it came out and considered it in	13	A Well, in this case the degree of
14	working on their designs?	14	perforation would be the full extent of of
15	MR. O'CONNOR: Form.	15	perforation, so the clock wouldn't start until the
16	THE WITNESS: I'm not aware	16	filter has achieved its designed shape.
17	MR. O'CONNOR: Foundation.	17	Q Okay. Meaning it's perforated so far
18	THE WITNESS: of that aspect.	18	through the vena cava of the subject patient that
19	BY MS. DALY:	19	it's regained its full size when it's fully
20	Q Now, the analysis that you did applying	20	deployed?
21	the Murphy paper data resulted in an estimate, if	21	A That's correct.
22	you look down towards the end of that first	22	Q How often does that happen in patients?
23	paragraph, it's about 6 lines 7 lines up, and it	23	A I don't know.
24	says "It would suggest that a filter arm	24	Q You assume it doesn't happen in everybody?
25	experiencing alternating strains of 1.38 percent in	25	MR. O'CONNOR: Form.
	Page 99	Ì	Page 101
1	a 14-millimeter-diameter vena cava"	1	THE WITNESS: I don't have any basis for
2	A Yes, I see that.	2	making any assumption at all.
3	Q "would last between 5,000 and 100,000	3	BY MS. DALY:
4	breaths or between 5.5 hours and 111 hours at 15	4	Q Okay. One way or the other?
5	breaths a minute."	5	A One way or the other.
6	A Yes.	6	Q Okay. Did you do any actual bench testing
7	Q Okay. 111 hours is less than five days,	7	with a Bard filter or any Bard filter to determine
8	right?	8	if your assumptions could be verified that
9	A Correct. Yep.	9	perforating struts of the filter to the maximum
10	Q Okay. So how many cases of fracture are	10	amount through vena cava tissue would lead to fast
11	you aware of that have been documented to have	11	failure?
12	occurred within 5.5 to 111 hours with Bard filters?	12	A I did no bench tests of that nature.
13	MR. O'CONNOR: Form and foundation.	13	Q If the condition that you're talking about
14	THE WITNESS: Well, I'm not I'm not	14	with full perforation first, let me back up.
15	I don't know results like that, but a point to be	15	When you're talking about the filter
16	made is that the clock starts when the full	16	getting to the point of having this full
17	perforation and endothelialization of the filter	17	perforation, are you talking about one strut?
18	has been achieved, so it's not a matter of counting	18	Multiple struts? All struts? What is what do
19	the time from the beginning of the filter being	19	you mean?
20	implanted in the patient but, rather, the time is	20	A Well, it would be at least two struts
21	counted from when the conditions that I assume have	21	opposite each other.
22	arisen.	22	Q Okay. On opposite sides?
23	BY MS. DALY:	23	A Opposite sides.
24	Q And when do those conditions arise?	24	Q Okay. So the condition starting this fast
25	A It could take quite some time for those	25	fracture would not be using a clock now, as we

	mite: Date ive in	in Re: Bard IVC Filters Products Liability				
	Page 102		Page 104			
1	obviously do with this, if the 12:00 and the 1:00	1	understand in terms of relationship between those			
2	side by side were doing that, that wouldn't start	2	two results. But either of those results can be			
3	the clock?	3	used to come up with the sort of information that			
4	A That wouldn't constitute the condition,	4	you're asking about.			
5	no.	5	Q Did their did their results on neutral			
6	Q They have to be on opposite sides, like a	6	breathing, were those consistent or different from			
7	3:00 and a 9:00?	7	what Murphy found?			
8	A Correct.	8	A I have to look at both papers to			
9	Q All right. And you don't know how often	9	Q Okay.			
10	perforation occurs with struts that are in	10	A try and answer that question.			
11	opposition to each other as opposed to side by	11	So the Murphy paper says that during			
12	side, true?	12	normal breathing, the area changed from 249			
13	MR. O'CONNOR: Form.	13	millimeters squared on average to 310 millimeters			
14	THE WITNESS: I don't know information or	1	squared on average. The numbers in the Laborda			
15	that.	15	paper are significantly higher. They find areas of			
16	BY MS. DALY:	16	400 meters squared, 380 meters squared, 342 meters			
17	Q You've seen you've seen cases where the	17	squared. So the areas, although they're not			
18	medical reports are that you've got two struts side	18	completely different, there's a difference in terms			
19	by side that might be perforating, true?	19	of the average areas which were observed.			
20	A That's correct.	20	Q So which which is larger?			
21	Q Now, Laborda study that was published in	21	A The I need to look at this carefully.			
22	2014, that talks about the Valsalva impact on	22	If I'm looking at the correct numbers, the			
23	changes in size of the vena cava, right?	23	numbers for the areas in the Laborda, et al., paper			
24	A That's correct.	24	are larger.			
25	Q And sort of the precursor of what they	25	Q And that paper was not available to			
	Page 103		Page 105			
1	then applied to the Celect and Tulip?	1	medicine or science until looks like it's			
2	A That's correct.	2	published October 2014, true?			
3	Q All right. Were their findings in that	3	A That's correct.			
4	paper any different with respect to contraction and	4	Q Now, with respect to Valsalva movements, I			
5	expansion of the vena cava than what they found	5	take it that you do not have any information about			
6	with the Celect filter in place?	6	how often any person with a Bard filter has a			
7	A Sorry, could you	7	Valsalva event?			
8	Q Yeah.	8	A No, I don't have any information on that.			
9	A repeat that question.	9	MR. O'CONNOR: Belated objection to the			
10	Q Yeah, Let's do it easier.	10	form.			
11	What did they find was the average	11	BY MS. DALY:			
12	expansion and/or contraction of the vena cava under	12	Q So at page 11, the last paragraph on that			
13	the effect of Valsalva?	13	page where you're talking about that Laborda paper			
14	A I'm going to read the Results	14	that we just discussed, which is Exhibit 13, you			
15	Q Sure.	15	say your calculation showed that a filter arm			
16	A section in the in the abstract.	16	experiencing those strains would last only about			
17	So they give results for the area during	17	500 Valsalva maneuvers before fracturing, correct?			
18	neutral breathing and the area during Valsalva.	18	A Which line is that on?			
19	Q Uh-huh.	19	Q Let me see where			
20	A And the ratio is approximately five, say,	20	A I see it. Yes, I see it. Yes, I agree.			
21	maybe four or five. So the area changes from	21	Q Okay. So do you know if there's a range			
22	from 100 percent down to about 25 percent according	22	amongst people who do have Valsalva movements of			
23	to these results on average. But then later on,	23	what the change in diameter would be?			
24	they make a comment that the collapsibility index is about .5, so there's something I don't quite	24	A Well, the information in the Laborda, et			
25	is about 5 as there's comothing I don't quite	25	al. paper indicates that that's the case because			

	In Re: Bard IVC Filters Products Liability				
	Page 106		Page 108		
1	there are ranges for the areas before Valsalva and	1	any such comment in the experts' reports that I		
2	there are ranges for the areas during Valsalva, so,	2	read, although I don't know if that can be ruled		
3	therefore, it suggests that there's a range of area	3	out, But, yeah.		
4	changes which occur because of Valsaiva.	4	Q Did you do you did you see anything		
5	Q So person to person there are differences?	5	in the literature that indicated that changes due		
6	A Yes.	6	to respiration, normal respiration, or Valsalva put		
7	Q You would agree?	7	strains on an IVC filter that resulted in tilt.		
8	A Yes.	8	migration or perforation?		
9	Q Similarly, person to person there are	9	A Well, there's a bench test study that Bard		
10	differences in what changes would happen in their	10	carried out in which they compared the Meridian		
11	anatomy in normal respiration; would you agree with	11	filter with some other filters, and they imposed		
12	that?	12	what would be representative of Valsalva changes of		
13	A I would agree with that.	13	shape to a synthetic vena cava and they found that		
14	MR. O'CONNOR: Form.	14	that caused tilt of the of the filters involved.		
15	BY MS. DALY:	15	So I think that's the only study I know where		
16	Q Okay.	16	anything like what you asked me about is is		
17	A Again, from the Murphy, et al. paper,	17	looked at.		
18	that's the suggestion.	18	Q And do you know what —		
19	Q Okay.	19	A Sorry, I should say the only one I'm aware		
20	A Or that's the indication, I should say,	20	of.		
21	yeah.	21	Q Do you know which filters in that test		
22	Q And of course the numbers of times people	22	performed any tilt in a Valsalva condition?		
23	have Valsalva movements during the time they have a	23	A I'd have to look at my report or		
24	Bard filter in situ would range greatly?	24	MR. O'CONNOR: Well, look at it.		
25	A I agree.	25	THE WITNESS: — look at the original		
2.5	<del>-</del>	23			
,	Page 107		Page 109		
1	MR. O'CONNOR: Form.	1	report to to to figure that out.		
2	BY MS. DALY:	2	BY MS. DALY:		
3	Q Okay. Have you seen any case that you	3	Q Yeah, I wasn't sure whether you meant it was with respect to the Meridian or something they		
4	A Can I revise that answer?	4			
5	Q Yes.	5	were comparing it to.		
6	A Although I agree from the position of a	6	A Well, they were doing comparisons, but my		
7	non-expert in what causes people to do Valsalva,	7	point of my answer was simply that they observed		
8	knowing what is involved in terms of what causes	8	the Valsalva maneuver sorry, the Valsalva		
9	Valsalva I can understand that there would be a	9	simulation in the experiment would cause the		
10	range of of numbers of times that an individual	10	Meridian to tilt and some other filters to tilt.		
11	would undergo such a maneuver.	11	Q Was it one Valsalva event?		
12	Q And, for example, if you had a respiratory	12	A No, it was multiple Valsalvas.		
13	problem and you were a chronic person that had to	13	Q Okay. And that test will tell us how		
14	do huge coughs, for example	14	often that was?		
15	A Yes. Yes.	15	A Yes.		
16	Q that's a Valsalva type, correct?	16	Q How many times it was		
17	A Yes, that's right.	17	A Yes.		
18	Q Okay. Do you know of any case that you	18	Q and what the pressures were, and so on?		
19	have looked at as an individual case in this	19	A Right, Correct.		
20	litigation where a doctor has reported that a	20	Q Okay. What about any either Bard testing		
21	patient had frequent Valsalva es episodes	21	or any literature that tells us whether changes		
22	between the time of implant and the time of	22	during normal respiratory behavior or Valsalva		
23	fracture of the filter?	23	caused perforation?		
24	A I didn't see any such information in the	24	A I know of no such study. I'm not aware of		
25	medical records that I studied, and I didn't see	25	it.		

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	In Re: Bard IVC Filt	ers r	Toducis Enability
	Page 110		Page 112
1	Q Or any Bard information?	1	Q Okay. At the increased strain levels that
2	A Or any Bard	2	you're describing, this 10 10 times greater, is
3	Q All right. Let's look a minute at page 9,	3	the assumption of linear elastic material response
4	paragraph 2 and 3. And we're talking about the	4	valid?
5	arms at the sheath and strains on the arms relative	5	A Well, the it depends on what the
6	to the sheath.	6	imposed level of of strain is, so if you take
7	A Right.	7	the nominal strain and multiply it by the strain
8	Q Okay. All right. One of your one of	8	concentration factor and that is below the limit to
9	your findings there is that "A strain concentration	9	linear elastic behavior, then the result is a
10	where the arm enters the sheath can elevate the	10	correct estimate of the strain concentrating effect
11	alternating strain in some cases by factors of 10	11	of the of the feature.
12	or more,"	12	If the nominal strain is higher and drives
13	Do you see that?	13	the strain at the in the strain concentration to
14	A I see that, yes.	14	higher than the limit on linear elastic strain,
15	Q What analysis did you perform to evaluate	15	then the calculation is not exactly correct.
16	that?	16	However, strain, because of its nature, since it's
17	A We carried out a finite element I	17	a geometric effect, the level of strain that you're
18	carried out well, it was with Professor Begley,	18	going to get when the material becomes nonlinear is
19	I carried out a finite element simulation of an arm	19	not going to be very different from the level of
20	touching the edge of the sheath where it where	20	strain that you get when the when the in
21	the arm entered the sheath, and the chamfer on the	21	terms of the strain concentration factor is not
22	cap we chose to be, as I recall, 5 microns and	22	going to be very different from what you predict
23	found that there were strain concentrations higher	23	using a purely linear analysis.
24	than 10.	24	Q But for the purpose of the work that you
25	Q That was your 2D FE?	25	did with these stress values, is it correct that
	Page 111	_	Page 113
1	A That was the 2D FE	1	the stress values you determined in your analysis
2	Q Okay.	2	rely on your assumption of a linear elastic
3	A finite element analysis.	3	response?
4	Q Did you present any calculations that	4	A Well, the the the strain levels in
5	demonstrate that the strain near the sheath would	5	the region where the strain has exceeded the limit
6	increase by that factor?	6	on linear elastic strain would be affected by the
7	A Sorry, could you repeat that question.	7	fact that there is nonlinear behavior beginning to
8	Q Yeah. Did you did you present any	8	set in. However, around the region where you have
9	actual calculations that demonstrated that the	9	nonlinear behavior, there is a zone in which the
10	strain near the sheath would increase by a factor	10	response is still linear because the strains are
11	of 10 plus?	11	low enough that the strains remain in the lineal
12	A I believe that we presented color contour	12	elastic regime, and those strains control the way
13	plots of the strains, and I'd have to review that	13	that the behavior occurs closer in to the to the
14	to see exactly what information is in it.	14	place where there is a high strain and constrain
15	MR. O'CONNOR: Are they here?	15	that motion and, as a result, the strain that you
		16	get at the strain concentration in the nonlinear
16	THE WITNESS: They're here, yeah.	17	material is relatively is little different from
17	BY MS. DALY:		what you get from the linear elastic analysis.
18	Q Yeah, and my next question was: Were	18	•
19	those results presenting stress or strain? So	19	And this is something that I've studied in
20	A Oh, I see.	20	my own research. It's it's a known consequence
21 22	These are stress plots.	21	of compatibility that is associated with the way
122	Q Okay. And did you use for that 2D FEA	22	materials deform.
23	analyzing the sheath interaction, did you use a	23	Q And you did not then take this analysis to

29 (Pages 110 - 113)

the point of a bench test to see if you could

actually measure strains of 10 times greater or

24

25

linear elastic material response?

A Yes.

24

25

	In Re: Bard IVC Filt	CI 2 L	Toducts Elability
	Page 114		Page 116
1	whatever?	1	fracture of a strut contacting the chamfer?
2	A No	2	A I would rely on them both where they're
3	MR. O'CONNOR: Form.	3	consistent with each other, and then I'd have to
4	THE WITNESS: I have not done such a	4	make a judgment if they came to different
5	bench test.	5	conclusions.
6	BY MS. DALY:	6	Q All right. Very good.
7	Q Okay. Now, we've talked about the chamfer	7	Are you same question about are you
8	issues in these cases	8	aware of examples of filter fracture caused by
9	A Yes.	9	wire-to-wire fretting or contact independently of
10	Q several times before.	10	whatever Dr. Fasching and Dr. Richie have found?
11	A Yes.	11	A I
12	Q Okay. Is it your opinion that any of the	12	MR. O'CONNOR: Form.
13	fractures of Bard filters where we've been able to	13	THE WITNESS: I don't have any independent
14	see the filters, or Richie and Fasching have seen	14	information on that.
15	the filters, have occurred from struts actually	15	BY MS. DALY:
16	coming in contact with a chamfer?	16	Q Okay. And if they do not have any
17	A Well, some of them appear to have been	17	examples of evidence of fracture from fretting wire
18	generated that way because the fracture surface is	18	to wire of any filters from G2X on to Denali, do
19	very close to being adjacent to the to the	19	you have anything more that you could give me for
20	chamfer and	20	evidence that that can occur in those filters?
21	Q And the information that you would have	21	A No.
22	about that would be based on the SEM work that	22	MR. O'CONNOR: Form.
23	either Dr. Fasching did or Dr. Richie, true?	23	THE WITNESS: I have nothing addition
24	A That's correct.	24	additional.
25	Q All right. Are you aware of any example	25	BY MS. DALY:
,	Page 115 of a fracture in a strut where there's evidence of	,	Page 117
I		1	Q Okay. The other thing that you and I
2	it coming in contact with the chamfer in a G2X,	2	talked about before, and Dr. Richie also comments
3	Eclipse, Meridian or Denali?	3 4	on, is strain concentrations in an area in the arm
4	A Sorry, could you repeat the question.		struts, as opposed to legs, sort of up towards the
5	Q Yes.	5	cap, correct? A Yes.
6	Are you aware of any Bard filter having a	6	·
7	strut fracture where there is evidence that that	7	Q All right. Do you agree with Dr. Richie
8	strut came in touch came in contact with the	8	that even if you see an explanted filter, you
1 1	chamfer in any G2X, Eclipse, Meridian or Denali?		cannot necessarily determine let me start over.
10	MR. O'CONNOR: Form. THE WITNESS: I would need to review	10	Let me start over.
11		11	In a filter that has not been retrieved,
12	Dr. Fasching's report and Dr. Richie's report to	12	are you aware of any way to determine the precise
13	see whether that's the case.	13	point at which that filter fractured?
14	BY MS. DALY:	14	A No.
15	Q Well, I will tell you that they have not	15	MR. O'CONNOR: Form.
16	looked at explanted Eclipse, Meridian or Denalis,	16	THE WITNESS: I'm not aware of any safe
17	and they've had a couple of G2Xs.	17	method that that would be feasible.
18	A So did you ask me about G2Xs?	18	BY MS. DALY:
19	Q Yeah.	19	Q Okay. And what about being able to look
20	A Well, then I'd have to review those	20	at the surface areas of two sides of fractures,
21	reports to see whether the G2X has that feature.	21	what's left with the filter and the and the
22	Q Would you rely on what Dr. Richie or	22	strut, in situ, you would agree that you can't do
23	Dr. Fasching found about whether there is an	23	that safely?
24	example or not an example of a filter with evidence		A You can't do it safely if both pieces are
25	of fracture a G2X filter with evidence of	25	still in the patient.

	III No. Bard IV C I'll		
١.	Page 118	1	Page 120
1	Q And would you also agree that if you do	1	A Yes.
2	not have retrieved filters and/or the fractured	2	Q "The possibility of strain concentration
3	strut, that again you cannot do an analysis to	3	should have been eliminated either by breaking,
4	determine what type of fracture it is?	4	curving or chamfering the edge in question at the
5	MR. O'CONNOR: Form.	5	mouth of the" "of the sheath."
6	THE WITNESS: I would say	6	We've talked earlier this morning about
7	MR. O'CONNOR: Foundation.	7	chamfer changes and the breaking or doing the
8	THE WITNESS: if you have one if you	8	beading, or whatever, to change that, correct?
9	either have a detached piece or if you have the	9	A Yes.
10	filter itself, you can do an analysis of the	10	Q All right. Do you think that there is a
11	fracture surface that you do have.	11	method by which Bard can eliminate strain
12	BY MS. DALY:	12	concentrations completely with respect to the
13	Q If you have neither?	13	chamfer?
14	A If you have neither, you you can't do	14	A Well, there's two ways. One is that you
15	it safely.	15	isolate the arms completely from the cap by holding
16	Q Okay.	16	the arms in some way so that they can't move close
17	A Or if it's or if the filter has	17	enough to the cap to contact it, and then you have
18	disappeared, you can't do it.	18	to be very careful about how you design how the
19	Q Right. All right.	19	arm goes into whatever's holding it because you
20	Are you aware of cases that you have	20	have to avoid strain concentrations there as well.
21	looked at in this litigation where there has been	21	And then you could do something such as
22	perforation or tilt in the absence of fracture?	22	was done for the Denali, which is that you would
23	A You mean one of the five cases that	23	make it from a tube so that the contact between
24	we're	24	what you would otherwise call a cap is is not a
25	Q No, I'm talking about	25	feature of what can happen. Although I should
		23	
	Page 119		Page 121
1	A In general.	1	comment that even those situations generate strain
2	Q in your whole experience with different	2	concentrations, but it may be very small.
3	cases.	3	So I suppose the simplest answer to your
4	A Can you repeat the question, please.	4	question is that you can't reduce strain
5	Q Yeah.	5	concentrations to one in any sort of feature that
6	Have you done any work given a report	6	has a complicated shape.
7	on any cases in this litigation where the	7	Q You cannot eliminate that prob that
8	complications were tilt and perforation only	8	problem?
9	without fracture?	9	A Yes, you can't eliminate strain
10	A "This litigation" meaning any	10	concentrations other than in the simplest
11	Q Bard filter cases.	11	Q Okay.
12	A case yeah, I I recall that there	12	A of shapes.
13	are some cases like that.	13	Q And you haven't tried to put together a
14	Q Do you recall there being some cases	14	prototype chamfer that would do that
15	you've worked on where there was a fracture and no	15	A No. No.
16	tilt?	16	Q that is, eliminate strains?
17	A I don't recall whether that's the case,	17	A No.
18	but I'm not sure.	18	Q Okay. Foot fractures, let's talk about
19	Q How about fracture and no perforation?	19	that for a minute. Dr. Richie recently testified
20	A Again I'm not sure. Yes, I'm not sure.	20	that he saw fewer foot fractures in the G2 filter.
21		21	Do you know if that's correct or not?
	Q On page 12 of your report, paragraph 4.	22	•
22	A Sorry, which page?		A I don't know independently whether that's
23	Q Page 12. Counting full paragraphs, I'm	23	correct or not.
24	looking at paragraph 4, and if you go down to line	24	Q Do you know if there was any modification
25	5 it starts with "For example."	25	to the G2 that from your engineering from an

	in Re; Bard IVC Fill	VIO 1	104400 224011119
	Page 122	1	Page 124
1	engineering standpoint may have reduced fracture to	1	Q And for for there to be additional
2	the feet?	2	strains on a leg that is missing a foot, would
3	A You mean from the Recovery to the G2?	3	there need to be some movement in the leg?
4	Q Yes, sir.	4	A Could you repeat the question.
5	A The ankle was thickened, and that would	5	Q Yeah.
6	have reduced the nominal strains that were present	6	If you've got a leg that's now missing a
7	in the material and then what would fall from that	7	foot, is it your opinion that the leg has to be
8	is the question of whether any gouge or other kind	8	moving in some way to have sufficient strain put on
9	of feature that would concentrate strains would	9	it that it would later fracture?
10	still elevate the strains to dangerous levels.	10	MR. O'CONNOR: Form.
11	Q Do you know how many foot fractures have	11	THE WITNESS: You mean would the vena cava
12	been reported with any of Bard's filters from the	12	wall have to move the leg in some way? It's my
13	G2 onto the Denali?	13	my
14	A I haven't studied that.	14	BY MS. DALY:
15	Q Okay. Do you have the opinion that a foot	15	Q Or the blood flow maybe. I don't know.
16	fracture causes tilt, migration, perforation or	16	A Say that again.
17	fracture?	17	Q Or blood flow.
18	A I have the opinion that a foot fracture	18	A Well, whatever whatever would cause the
19	would lead to tilt, and since it's my assessment	19	deformation, there would have to be some sort of
20	that tilt leads to perforation I think that would	20	distortion that would take place for a fatigue
21	then be a second consequence. And since it's my	21	fracture to follow because fatigue fracture is
22	opinion that a perforation can lead to fracture, I	22	generated by strain, strain changes.
23	think that that would be a follow-on consequence	23	Q Have you identified any case that you've
24	of of a foot fracture.	24	worked on thus far that had a foot fracture that
25	Q What if the what if the leg is	25	you believe led to a later leg fracture?
	Page 123		Page 125
1	perforating to the point that you've discussed	1	A I haven't
2	before, that is the filter's now all the way out to	2	MR. O'CONNOR: Form.
3	its former or greatest extent that it could be	3	THE WITNESS: studied that.
4	out, would you expect a foot fracture to contribute	4	BY MS. DALY:
5	to tilt or migration?	5	Q In what percentage of foot fractures does
6	A Well	6	migration of the filter occur?
7	MR. O'CONNOR: Form. Foundation.	7	A I don't know.
8	THE WITNESS: My assessment is the foot	8	MR. O'CONNOR: Form.
9	fracture would have taken place while the foot was	9	BY MS. DALY:
10	still engaged with the vena cava wall, and,	10	Q When Bard electropolished the Eclipse
11	therefore, when it was broken it would have had an	11	filter, did that have any impact on improving the
12	impact on the stability of the filter. But once	12	resistance to foot fracture?
13	perforation has taken place and any tilt that's	13	MR. O'CONNOR: Form.
14	associated with that, then the implications would	14	THE WITNESS: I don't know for for
15	be less direct and probably not involved at all.	15	sure, but in principle it would have improved the
16	BY MS. DALY:	16	resistance to foot fracture.
17	Q So do you know if when a foot fractures if	17	BY MS. DALY:
18	the leg on which it was, that leg starts moving	18	Q And how so?
19	freely within the vena cava? Do you know that?	19	A Because it smooths the surface and makes
20	A You mean does it move by large amounts?	20	the initiation of fatigue cracks somewhat less
21	Q Or does it move at all?	21	likely.
22	MR. O'CONNOR: Form.	22	Q And again, you don't know about the
23	THE WITNESS: I I don't know for any	23	numbers of events of foot fractures reported in
24	certainty that that's the case.	24	Eclipse, for example?
25	BY MS. DALY:	25	A No. No.

	III No. Data IVC I'll	·	<del></del>
١.	Page 126	1	Page 128
1	Q Okay. What causes what causes failure	1	A Right. And the stiffness
2	of legs in Bard filters?	2	MR. O'CONNOR: Form.
3	A Well, one possibility is the blood clots	3	THE WITNESS: we're now talking about
4	repeatedly impact the filter, and even a single	4	is is more or less the axial stiffness of the
5	blood clot, as the blood flows up and down not	5	vena cava, not the stiffness in the circumferential
6	down, but as the pulsatile flow of the blood moves		direction.
7	the clot around, that would push the clot against	7	BY MS. DALY:
8	the leg multiple times and so that could cause	8	Q And stiffness of a vena cava could be a
9	that would cause strain strain increments to	9	range of stiffness being patient-dependent, true?
10	the to the material in the leg that could	10	A Yes.
11	ultimately cause it to fracture by fatigue.	11	MR. O'CONNOR: Form.
12	There's another possibility, which is that	12	BY MS. DALY:
13	if the arms and the legs are endothelialized to the	13	Q And it could also be impacted by organs?
14	wall of the vena cava and the vena cava is stiff	14	A Yes.
15	enough to resist axial motion of the points where	15	Q And the stiffness of those organs
16	the arms and the legs are glued to the wall of the	16	contributing to vena cava stiffness could be
17	vena cava, it can cause some additional strains on	17	patient-specific?
18	the legs, and on the arms for that matter, because	18	A Yes.
19	of the constraint that makes it more difficult for	19	Q Okay.
20	the filter to respond to the expansion and	20	A Can I add one amplification of my answer,
21	contraction of of the vena cava. So that's	21	which is that let's say that an arm and a leg an
22	another possibility for where leg fractures can	22	arm and a leg are perforated and they get inserted
23	come from,	23	into, say, the vertebrae and they get firmly
24	Q So the first one that you talked about is	24	connected to the vertebrae and now the vena cava's
25	your water hammer	25	expanding and contracting, that could be a very
	Page 127		Page 129
1	A That's right.	1	severe stiffness constraint on whether the relative
2	Q theory.	2	motion of the arms and the legs can be accommodated
3	A Well, it's not my water hammer theory	3	as the filter, if you like, tries to stretch. So
4	well, first of all, it's not my theory. But	4	that that's a possibility.
5	secondly, it's not only my water hammer model but	5	Q Do you have any case that you can point to
6	it is it is a consequence of the actions of the	6	that you have worked on where there was imaging
7	clots on the filter which in one interpretation can	7	evidence of perforation, tilt or migration that
8	be looked at in terms of water hammer.	8	occurred before a leg fracture?
9	Q Okay. We're going to talk about that in a	9	A I haven't looked into that.
10	separate thing in a moment.	10	MR. O'CONNOR: Belated objection to the
11	So the second thing you're talking about	11	form of the question.
12	that could lead to leg fracture is you've got	12	BY MS. DALY:
13	perforating legs; am I getting this right?	13	Q Have you done any work to determine what
14	A Perforated or unperforated, but they're	14	modifications Bard could have made to the legs
15	endothelialized to the wall of the vena cava.	15	themselves to improve on those legs' contribution,
16	Q So they're not moving?	16	if any, to tilt, perforation, fracture or
17	A They're moving because the vena cava is	17	migration?
18	expanding and contracting, but otherwise their	18	A No, I haven't looked into that.
19	relative motion is constrained.	19	Q We've talked a little bit about the
20	Q And, in addition, the vena cava is stiff	20	anchors and limiters present on the Meridian. Is
20 21	enough that on those constrained legs, let's talk	21	it your opinion that those are reasonable
22	about legs for a minute, that there's a possibility	22	modifications by Bard to to improve resistance
23	that could cause fracture?	23	to migration, tilt and perforation?
	_	23 24	
24			A It's a reasonable concept for how the tilt
25	Q Do I have that right?	25	and migration behavior can become can be

	In Re: Bard IVC Filt	ers I	Products Liability
	Page 130		Page 132
1	limited.	1	A I have no opinion on that because I have
2	Q Would do you have an opinion whether	2	not studied it.
3	those anchors or limiters on the Meridian would add	3	Q Okay. Have you studied what the mechanism
4	fracture resistance to that filter?	4	is anatomically to create caudal migration in any
5	A I have no opinion on that.	5	Bard filter?
6	Q Same questions with Denali, do you think	6	A I've not studied that independently.
7	that the limiters that the Denali has will act to	7	Q Okay.
8	improve resistance to migration, tilt, perforation	8	A I've only
9	and fracture?	9	O What does that mean?
10	MR. O'CONNOR: Form.	10	A What does it mean. I've looked at the
11	THE WITNESS: It's it is reasonable to	11	Bard report of their bench test
12	expect that there will be some effect on on tilt	12	Q Okay.
13	and migration and that those would have possible	13	A and which is suggestive of a
14	knock-on consequences to perforation and fracture.	14	mechanism that can drive caudal migration.
15	And so I'd like to revise my answer about the	15	Q Okay.
16	Meridian in the same way, that the caudal anchors,	16	A Because it's because it's associated
17	to the extent they limit tilt and migration, they	17	with tilt.
	• • • • • • • • • • • • • • • • • • • •	18	
18	could have beneficial effects on perforation and	1	Q Okay. And have you done any work to
19	fracture.	19	determine how Bard might have modified its filters
20	BY MS. DALY:	20	to reduce tilt that you associate with caudal
21	Q Okay. What modifications to the G2 filter	21	migration, with contributing to caudal migration?
22	assisted in resistance to cephalic migration? Do	22	MR. O'CONNOR: Form.
23	you have an opinion on that?	23	THE WITNESS: Well, the only observation I
24	MR. O'CONNOR: Form.	24	have is that the effective caudal anchors would
25	THE WITNESS: I'm not aware of any changes	25	have had a beneficial effect, but otherwise I've
	Page 131	١.	Page 133
1	that would have had an impact on cephalic	1	done no thinking or studying of that.
2	migration.	2	BY MS. DALY:
3	BY MS. DALY:	3	Q All right. If you look at your report,
4	Q Are you aware that the incidents of	4	page 13, it's the G2 Express filter.
5	cephalic migration of G2 and later Bard filters	5	A Yes.
6	has has improved greatly?	6	Q We've talked about the cap change I think
7	A I'm not aware of that.	7	exhaustively.
8	Q What about the change to the G2 filter	8	A Yes.
9	contributed to caudal migration, if you have an	9	Q And did you have any other observation of
10	opinion?	10	the G2 Express as as having characteristics that
11	MR. O'CONNOR: Form.	11	that particular filter had that contributed to any
12	THE WITNESS: Sorry, can you repeat the	12	of these complications different from Recovery and
13	question.	13	G2?
14	BY MS. DALY:	14	A Well, the cap sorry, the hook on the
15	Q Yeah.	15	cap, because it would have touched during tilt
16	Do you have an opinion about whether any	16	it would have been touched, under certain
17	design modification that Bard made to the G2 filter	17	assumptions about how the filth occurs, it would
18	resulted in caudal migration?	18	have touched the wall of the vena cava first as
19	A You mean going from the Recovery to the G2	19	opposed to other points on the cap, and that would
20	filter —	20	have had some effect on what happens in terms of
21	Q Yeah.	21	perforation and tilting of the of the filter.
22	A whether that improved caudal migration?	22	And it's my assumption that the big hook
23	Q No, whether it caused it.	23	would have taken would have been would have
24	A Whether it contributed to it.	24	taken longer to perforate through the wall of the
25	Q Yes.	25	vena cava than the cap itself, although that's just
	× 100.		

	III Re. Daid IVC File		<del>`</del>
	Page 134	,	Page 136
1	an assumption, it's not a it's not anything	1	degree to which that issue contributed to any
2	definitive.	2	fractures in Recovery or G2?
3	Q And if the hook took longer to perforate,	3	A No, I have no opinion about that.
4	how would that impact any of these complication	4	Q Okay. Would you leave that to Dr. Richie
5	events?	5	to discuss?
6	A Well, to the extent the tilt contributes	6	A Yes, I would.
7	to fracture, it would have helped to reduce the	7	Q All right.
8	tendency for fracture to occur.	8	A Although can I make one further comment?
9	Q Okay.	9	Q Of course.
10	A But I don't think that would have been a	10	A That she gave me a shape of a gouge, I
11	big effect, but that that's a possibility.	11	could then estimate the strain concentration, but
12	Q Do you understand from your reading or	12	other than that I would not look at that question.
13	looking at any design drawings that the inclusion	13	Q Do you know whether surface conditions
14	of the hook on the G2X was at the recommendation of	14	were of particular great moment to contribution for
15	user doctors who felt it was a an improvement to	15	fractures in G2s or Recoveries?
16	methods for retrieval?	16	A I don't know
17	MR. O'CONNOR: Form and foundation.	17	MR. O'CONNOR: Form.
18	THE WITNESS: I've seen comments in	18	THE WITNESS: I just leave that to
19	various documents that say it has improved	19	Dr. Richie.
20	retrievability.	20	BY MS. DALY:
21	BY MS. DALY:	21	Q Okay. Did the electropolishing of the
22	Q You don't hold an opinion on it?	22	Eclipse have any other positive impact on
23	A I have no opinion on it.	23	resistance to any other complication? We've talked
24	Q We've talked about the Eclipse and	24	about feet, but what about electropolishing
25	electropolishing. And if you look at page 15 of	25	contributing to resistance to perforation,
	Page 135		Page 137
1	your report, full paragraph 1.	I	migration or tilt?
2	MR. O'CONNOR: What page?	2	A Other than reducing the number of
3	MS. DALY: 15.	3	fractures to whatever extent that occurs, I
4	Q In the first about five or six lines	4	don't I can't think of any consequence that the
5	you're talking about that change, and then you say	5	electropolishing would have had. It might have had
6	"I would expect a marginal improvement in terms of	6	some consequence to epithelialization, but other
7	incidents of fatigue fractures in the Eclipse	7	than that I don't see any direct consequence.
8	model."	8	Q Okay. And I guess what you're saying,
9			
1	A Yes.	9	too, is if if your hypothesis is correct that
10	A Yes.  Q And what do you mean by "a marginal	9 10	fracture equals tilt or other things, if it didn't
-			· · · · · · · · · · · · · · · · · · ·
10 11 12	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm	10	fracture equals tilt or other things, if it didn't
10 11 12 13	Q And what do you mean by "a marginal improvement"?	10 11	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from
10 11 12	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm	10 11 12	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example
10 11 12 13	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific	10 11 12 13	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.
10 11 12 13 14	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of	10 11 12 13 14	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example
10 11 12 13 14 15	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the	10 11 12 13 14 15	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.
10 11 12 13 14 15	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the electropolishing. So I'm not being very clear on	10 11 12 13 14 15 16	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.  THE WITNESS: if a fracture was
10 11 12 13 14 15 16 17	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the electropolishing. So I'm not being very clear on this.	10 11 12 13 14 15 16	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.  THE WITNESS: if a fracture was would have otherwise contributed to tilt and
10 11 12 13 14 15 16 17	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the electropolishing. So I'm not being very clear on this.  So if you take a certain number of filters	10 11 12 13 14 15 16 17	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.  THE WITNESS: if a fracture was would have otherwise contributed to tilt and perforation, then that consequence would have been
10 11 12 13 14 15 16 17 18	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the electropolishing. So I'm not being very clear on this.  So if you take a certain number of filters that are going to fail without electropolishing,	10 11 12 13 14 15 16 17 18	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.  THE WITNESS: if a fracture was would have otherwise contributed to tilt and perforation, then that consequence would have been eliminated to some extent.
10 11 12 13 14 15 16 17 18 19 20	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the electropolishing. So I'm not being very clear on this.  So if you take a certain number of filters that are going to fail without electropolishing, the number of filters that would fail with	10 11 12 13 14 15 16 17 18 19	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.  THE WITNESS: if a fracture was would have otherwise contributed to tilt and perforation, then that consequence would have been eliminated to some extent.  BY MS. DALY:
10 11 12 13 14 15 16 17 18 19 20 21	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the electropolishing. So I'm not being very clear on this.  So if you take a certain number of filters that are going to fail without electropolishing, the number of filters that would fail with electropolishing would not be that much different	10 11 12 13 14 15 16 17 18 19 20 21	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.  THE WITNESS: if a fracture was would have otherwise contributed to tilt and perforation, then that consequence would have been eliminated to some extent.  BY MS. DALY:  Q Okay. Meridian, you talk about that at
10 11 12 13 14 15 16 17 18 19 20 21 22	Q And what do you mean by "a marginal improvement"?  A Well, I mean a small improvement. I'm not I I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the electropolishing. So I'm not being very clear on this.  So if you take a certain number of filters that are going to fail without electropolishing, the number of filters that would fail with electropolishing would not be that much different as yeah, not much not that much different.	10 11 12 13 14 15 16 17 18 19 20 21 22	fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?  A Yeah, I'm yes. For example MR. O'CONNOR: Form.  THE WITNESS: if a fracture was would have otherwise contributed to tilt and perforation, then that consequence would have been eliminated to some extent.  BY MS. DALY:  Q Okay. Meridian, you talk about that at page 16 of your report at the bottom. And you note

г	In Re. Bard IVC Fill		
	Page 138		Page 140
	A I yes, that's correct.	1	talking about.
2	Q And do you know what the purpose of those	1	Q Okay. What's another example?
3	two different placements of anchors was?	3	A That it didn't account for combinations of
4	A I don't know definitively, but I've	4	tilt and perforation. It didn't account for the
5	I've made a I feel like a guess as to why that	5	effect of endothelialization.
6	was done.	6	Q Okay. Do you know if any other IVC filter
7	Q And what do you think was the reason?	7	manufacturer tests with those combined types of
8	A I think it was let me let me look at	8	issues?
9	what I say. Yeah, it would deal with vena cava	9	A I'm not allowed to comment.
10	diameters of different size with, and I'm making	10	Q Okay. So you're not going to rely on what
11	the guess, that the ones at the wrist will help to	11	some other company is doing to say Bard could have
12	inhibit caudal migration and larger-diameter vena	12	done this?
13	cavas and the ones at the elbow will help to	13	A No.
14	inhibit caudal migration in smaller-diameter	14	Q And you have not developed test protocols
15	vessels.	15	to try out, to see if one can successfully test for
16	Q All right. If you look at page 17, it's	16	perforation with a tilt and what happens for
17	first and second full paragraphs, you're talking	17	strains or any other combination?
18	about Meridian bench testing.	18	MR. O'CONNOR: Form.
19	A Yes.	19	BY MS. DALY:
20	Q Okay. And you talk about you say Bard	20	Q True?
21	used a more aggressive protocol for certain tests	21	A That's correct.
22	on Meridian that it did not use I guess on earlier	22	Q On page 19, paragraph 2, it's I wanted
23	filters? Is that what your point is.	23	to ask you about five lines from the bottom six,
24	A That's my point, yeah, that yes.	24	actually. You're talking about "I note that no
25	Q But then you're still critical of the	25	changes were made to the Meridian design that would
	Page 139		Page 141
1	Meridian testing. Can you explain that to me?	1	improve cephalic migration resistance."
2	A Well, the Meridian testing was not done in	2	Do you see that?
3	what would be identifiable as worst-case	3	A Yes, I see that.
4	conditions, so perforation was not accounted for in	4	Q Is that because your understanding is
5	the fatigue tests. There may well, I don't	5	those anchors will only prevent caudal migration?
6	recall whether tilt was allowed for in the fatigue	6	A Yes, that's right.
7	tests, but combinations of of tilt and	7	Q Okay. Have you seen any tests about
8	perforation were not allowed for, so aspects like	8	Meridians having being tested for cephalic
9	that were deficiencies in the approach to the	9	migration?
10	testing.	10	A I don't recall seeing any tests like that.
11	Q So your criticism is that you don't	11	Q Do you know of any incidents reported
12	believe they did it to worst case?	12	where Meridian filter has migrated cephalically?
13	A That's correct.	13	A I I don't recall.
14	Q All right.	14	Q And you of course have not tested the
15	A And but in addition, they didn't design	15	Meridian in any way?
16	the test to identify failure conditions, and,	16	A No, not at all.
17	therefore, they they did not have a basis on	17	Q Let's look at your supplemental report of
18	which to determine whether the test was realistic	18	April 17 (sic), '17. It's Exhibit 3, page 2.
19	in truly assessing the failure and the mechanisms	19	A Exhibit 3? Thank you.
20	of failure which were possibly present in the	20	Q Yes.
21	filter.	21	A Which page?
22	Q So you're critical, for example, that the	22	Q On page 2 of your report.
23	testing didn't simulate perforation? Is that what	23	A Okay.
24	you're saying, by way of an example?	24	Q And I think I wanted to ask you

			<u> </u>
	Page 142	1	Page 144
1	find it.	1	the vena cava, not of tilt.
2	Go ahead and start. I'll find it.	2	Q And we talked about that?
3	BY MS. DALY:	3	A We talked about that.
4	Q You're you're talking about an FEA by	4	Q Okay. So going back to your main report
5	Harrison at the top of that page.	5	again, I'm on page 18, paragraph 2, that first line
6	A Yes.	6	you say that "In one of the caudal migration tests,
7	Q To obtain conservative results for the	7	the bar was set very low by Bard as to what was
8	magnitudes of alternating strains.	8	required of Meridian."
9	What is your criticism there on that	9	What do you mean by that?
10	testing relative I mean that FEA relative to the	10	A Can you tell me which paragraph we're in?
11	Meridian? The same things we're talking about with	11	Q Yeah. It's the second full paragraph, the
12	respect to the testing that we just talked about or	12	first sentence, on page 18.
13	something different?	13	A Well, I mean that it the the test
14	A Okay. So when I say he's imposed a rigid	14	was simply to compare the caudal migration of the
15	constraint, this is the question of rotation of the	15	Meridian with the caudal migration behavior of the
16	arm relative to the wall of the vena cava as the	16	Eclipse.
17	expansion and contraction of the vena cava takes	17	Q Okay.
18	place, which would effectively double the level of	18	A And since the caudal anchors would have an
19	strain generated by that motion.	19	effect on the tendency for caudal migration to take
20	Q And you have not done an FEA to see if in	20	place in the Meridian, it was almost certain that
21	fact that would double the strains as well, right?	21	the Meridian would have better performance than the
22	MR. O'CONNOR: Object to the form.	22	Eclipse.
23	THE WITNESS: Well, I've not done a finite	23	Q Sure. So why was that setting the bar
24	element analysis, but that's not necessary to do	24	low? I guess I'm not following you.
25	because the Euler-Bernoulli bead analysis provides	25	A Well, it was simply comparison between a
-	<u> </u>	-	
1	Page 143 you with that result.	1	Page 145 filter that should have had better performance with
2	BY MS. DALY:	2	one that that that did not have that level of
3	Q And then you have, of course, not done any	3	performance, as opposed to a test in which there
4	bench testing on the Meridian to see how it would	4	was an objective criterion for what for what was
5	really hold up in actual testing?	5	adequate resistance to caudal migration.
6	A No, I've done no bench testing.	6	Q Okay. So you don't know what those values
7	MR. O'CONNOR: Belated objection to the	7	are, in other words, you don't know what the
8	form of the question.	8	Meridian's caudal migration resistance is by load
9	BY MS. DALY:	9	or anything, right?
10		ı	or any uning, right:
	O So to that point you're you're	l 10	A. Wall other than the regults from that
11	Q So to that point, you're you're	10	A Well, other than the results from that
11	making you're just critical that the same	11	bench test, no.
12	making you're just critical that the same erroneous, according to you erroneous, variables	11 12	bench test, no.  Q Okay.
12 13	making you're just critical that the same erroneous, according to you erroneous, variables were used?	11 12 13	bench test, no.  Q Okay.  A I don't know.
12 13 14	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions.	11 12 13 14	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?
12 13 14 15	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions.  Q Assumptions	11 12 13 14 15	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.
12 13 14 15 16	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions.  Q Assumptions  A Yes.	11 12 13 14 15 16	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?
12 13 14 15 16 17	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions. Q Assumptions A Yes. Q were used?	11 12 13 14 15 16 17	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?  MR. O'CONNOR: Form and foundation.
12 13 14 15 16 17	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions. Q Assumptions A Yes. Q were used? A Correct.	11 12 13 14 15 16 17 18	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?  MR. O'CONNOR: Form and foundation.  THE WITNESS: I won't comment.
12 13 14 15 16 17 18 19	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions. Q Assumptions A Yes. Q were used? A Correct. Q But we've already talked about those?	11 12 13 14 15 16 17 18 19	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?  MR. O'CONNOR: Form and foundation.  THE WITNESS: I won't comment.  BY MS. DALY:
12 13 14 15 16 17 18 19 20	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions. Q Assumptions A Yes. Q were used? A Correct. Q But we've already talked about those? A Yes, we have.	11 12 13 14 15 16 17 18 19 20	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?  MR. O'CONNOR: Form and foundation.  THE WITNESS: I won't comment.  BY MS. DALY:  Q You just don't know?
12 13 14 15 16 17 18 19 20 21	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions. Q Assumptions A Yes. Q were used? A Correct. Q But we've already talked about those? A Yes, we have. Q Yes.	11 12 13 14 15 16 17 18 19 20 21	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?  MR. O'CONNOR: Form and foundation.  THE WITNESS: I won't comment.  BY MS. DALY:  Q You just don't know?  A I don't know.
12 13 14 15 16 17 18 19 20 21 22	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions.  Q Assumptions  A Yes.  Q were used?  A Correct.  Q But we've already talked about those?  A Yes, we have.  Q Yes.  A But I note further down the paragraph,	11 12 13 14 15 16 17 18 19 20 21 22	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?  MR. O'CONNOR: Form and foundation.  THE WITNESS: I won't comment.  BY MS. DALY:  Q You just don't know?  A I don't know.  Q All right. In your back to your
12 13 14 15 16 17 18 19 20 21 22 23	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions.  Q Assumptions  A Yes.  Q were used?  A Correct.  Q But we've already talked about those?  A Yes, we have.  Q Yes.  A But I note further down the paragraph, there's other comments, which is that the Harrison	11 12 13 14 15 16 17 18 19 20 21 22 23	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?  MR. O'CONNOR: Form and foundation.  THE WITNESS: I won't comment.  BY MS. DALY:  Q You just don't know?  A I don't know.  Q All right. In your back to your  4-7-17, Exhibit 3 report, still on Meridian but on
12 13 14 15 16 17 18 19 20 21 22	making you're just critical that the same erroneous, according to you erroneous, variables were used?  A Assumptions.  Q Assumptions  A Yes.  Q were used?  A Correct.  Q But we've already talked about those?  A Yes, we have.  Q Yes.  A But I note further down the paragraph,	11 12 13 14 15 16 17 18 19 20 21 22	bench test, no.  Q Okay.  A I don't know.  Q And you haven't tried to do that yourself?  A No, I have not.  Q So it may be fantastic?  MR. O'CONNOR: Form and foundation.  THE WITNESS: I won't comment.  BY MS. DALY:  Q You just don't know?  A I don't know.  Q All right. In your back to your

	In Re: Bard IVC Filt	CI 2 I	Toducts Endomity
	Page 146		Page 148
1	A Correct.	1	differences in the from the previous iterations,
2	Q In the Nissan/Romano paper, they detected	2	true?
3	two arm fractures in a single Meridian, correct?	3	A Yes.
4	A That's correct.	4	Q All right. And you are still highly
5	Q And then in the Wu paper, they detected an	5	critical of the Denali filter why?
6	arm fracture one year after implant in the	6	A Because it it wasn't changed well,
7	Meridian; is that right?	7	although there's lots of differences, it wasn't
8	A That's correct.	8	changed that much from the basic shape of the
9	Q And you note that there has been no	9	Meridian filter, and, therefore, its basic behavior
10	examination, apparently, of either the filter from	10	in the same circumstances as the Meridian filter
11	which the fracture happened or the fractured piece	11	would have been quite similar.
12	in either of those Meridians to tell us what type	12	Q It has a different cap?
13	of fracture that was; is that fair?	13	A Yes.
14	A Yeah, I	14	Q It does not have the the chamfer
15	MR. O'CONNOR: Form.	15	contact possibility that previous ones did, true?
16	THE WITNESS: don't know examination.	16	A I agree that there are some changes that
17	BY MS. DALY:	17	eliminate some aspects of the expected behavior,
18	Q Okay. And you quote to those events for	18	but what I'm saying is that many of the of the
19	what purpose?	19	features of the behavior would have been left
20	A Just to identify the fact that that	20	unchanged because of the basic similarity in shape
21	Meridian filters can fracture in vivo.	21	of the Denali filter to the Meridian filter.
22	Q Does does two reports of Meridian, or	22	Q To what extent can the Denali perforate?
23	even more than two reports, support that it's prone	23	A I you mean what is the rate of
24	to fracture?	24	perforation?
25	A I think it does with the definition that	25	Q Yeah.
	Page 147		Page 149
1	"prone" means it can happen.	1	A I don't have any information on that.
2	Q Okay. So that's your definition, it can	2	Q What about its ability to migrate either
3	happen?	3	cephalad or caudal, do you have any information on
4	A Yes.	4	that?
5	Q "Prone" means can happen, not is likely to	5	A I have no direct information on that.
6	happen?	6	Q So your criticism is that there are
7	MR. O'CONNOR: Form.	7	aspects of the Denali that in your opinion will
8	THE WITNESS: It I I would just	8	allow it make it that it can tilt, perforate,
9	repeat my definition, that prone to fracture means	9	fracture or migrate?
10	it can happen.	10	A Yes. And I I I should comment that
11	BY MS. DALY:	11	there is some description of of events for the
12	Q Can happen. Is it more likely than not to	12	Denali in the supplementary report.
13	happen in a Meridian?	13	Q Right. Right. And I'm going to
14	A I don't know whether that's the case.	14	A I don't mean to ignore
15	Q Have you ever used the term prone to	15	Q get to those.
16	fracture, tilt, perforate or migrate relative to a	16	A that.
17	Bard filter where your def where your	17	Q Yeah, I'm going to get to those.
18	definition was something other than can happen?	18	Okay. Do you know of modifications to the
19	A I don't believe so.	19	Bard filters, any of them, that would have made
20	Q All right. On to Denali, and back, I'm	20	them unable to fracture, tilt, perforate or
21	sorry, to your March report, Exhibit 2, page 20.	21	migrate?
22	On page 20 you give sort of an overview of the	22	MR. O'CONNOR; Object to the form of the
23	changes to the Denali filter?	23	question.
ı	A 37		M I b tbti 11
24 25	A Yes. Q Okay. And it's there are a lot of	24 25	May I hear the question back again. THE WITNESS: Could you repeat the

	Deep 150	Г	Page 152
1	Page 150 question.	1	Page 152 Q Yeah.
2	MS. DALY: Can you read that one.	2	A I'm still at Table 2.
3	(Record read as follows:	3	Q Okay.
4	"Do you know of modifications to	4	A Table 4.
5	the Bard filters, any of them,	5	Q Okay. The data from that study showed
6	that would have made them unable	6	zero fractures in the Denali?
7	to fracture, tilt, perforate or	7	A I yes.
8	migrate?")	8	Q Zero migrations?
9	THE WITNESS: I haven't studied that.	9	A Yes. Zero migrations greater than 2
10	BY MS. DALY:	10	centimeters.
11	Q So you you do not have an opinion that	11	Q Yes. Zero tilts greater than 15 degrees
12	there was a method by which Bard could eliminate	l	Or
13	tilt, fracture, perforation or migration in any one	13	A Yes, zero tilt greater than 15 degrees.
14	of its iterations from Recovery to Denali?	14	Q Three penetrations at implant?
15	MR. O'CONNOR: Form and foundation.	15	A Yes.
16	THE WITNESS: You mean simultaneously	16	Q And two penetrations at retrieval?
17	eliminate all of those negatives?	17	A Well, 3 out of 200 at placement, 2 out of
18	MR. O'CONNOR: Form.	18	121 at retrieval.
19	BY MS. DALY:	19	Q Okay. I read that right?
20	Q Or one by or any of them, either all of	20	A Yes.
21	them or, yes, you could you could have	21	Q Yes. Okay.
22	eliminated completely this, this or this.	22	Then in your Denali-specific report, which
23	A Well, I I think it's possible to	23	is the April report, back to Exhibit 3
24	eliminate one of the phenomena by itself but	24	A Okay.
25	Q What's that?	25	Q page 7 at Section 2.2. Yeah, top of
<u> </u>	Page 151		Page 153
1	A Possibly perforation.	1	the page, 2.2.
2	Q And how would you do that?	2	A Yes.
3	A Make a big penetration limiter.	3	Q You report on a case report by Dr. Kuo of
4	Q Okay. And you had not done a prototype of	4	a Denali fracture, correct?
5	that, correct?	5	A In the Kuo and Robertson paper. Is that
6	A No, I have not.	6	what you're
7	Q You have not determined what other	7	Q Yes.
8	unintended consequences it might have to the design	8	A Yes.
9	or benefits of the filter?	9	Q And then there's a paper by
10	A No, I haven't studied that.	10	Sathyanarayana I will spell that later of one
11	Q All right. With respect to Denali, we	11	Denali fracture, correct?
12	talked earlier today about Dr. Stavropoulous's	12	A Can you remind me how far down that one
	and the first the distance the last site 10	13	is.
13	study, the final he did the clinical trial?		== <i>r</i>
13 14	A Yes. Correct.	14	Q Yeah, he's
14	A Yes, Correct,	14	Q Yeah, he's
14 15	A Yes, Correct, Q Okay, And if you would look at that	14 15	Q Yeah, he's A We're on page 7?
14 15 16	A Yes, Correct, Q Okay. And if you would look at that again. I forget what we've numbered that,	14 15 16	Q Yeah, he's A We're on page 7? Q Yeah. Where is Sathyanar
14 15 16 17	A Yes. Correct.  Q Okay. And if you would look at that again. I forget what we've numbered that.  A Oh, do I still have it? Yes, I do.	14 15 16 17	Q Yeah, he's A We're on page 7? Q Yeah. Where is Sathyanar MR. O'CONNOR: What report are we looking
14 15 16 17 18	A Yes, Correct. Q Okay. And if you would look at that again. I forget what we've numbered that. A Oh, do I still have it? Yes, I do. Q Is it there?	14 15 16 17 18	Q Yeah, he's A We're on page 7? Q Yeah. Where is Sathyanar MR. O'CONNOR: What report are we looking at again?
14 15 16 17 18 19	A Yes. Correct.  Q Okay. And if you would look at that again. I forget what we've numbered that.  A Oh, do I still have it? Yes, I do.  Q Is it there?  A Yes. No. 12.	14 15 16 17 18 19	Q Yeah, he's A We're on page 7? Q Yeah. Where is Sathyanar MR. O'CONNOR: What report are we looking at again? MS. DALY: The April one.
14 15 16 17 18 19 20	A Yes. Correct. Q Okay. And if you would look at that again. I forget what we've numbered that. A Oh, do I still have it? Yes, I do. Q Is it there? A Yes. No. 12. Q Okay. 12. If you look at Table 4 on page	14 15 16 17 18 19 20	Q Yeah, he's A We're on page 7? Q Yeah. Where is Sathyanar MR. O'CONNOR: What report are we looking at again? MS. DALY: The April one. THE WITNESS: Supplementary report, April
14 15 16 17 18 19 20 21	A Yes. Correct. Q Okay. And if you would look at that again. I forget what we've numbered that. A Oh, do I still have it? Yes, I do. Q Is it there? A Yes. No. 12. Q Okay. 12. If you look at Table 4 on page 7 of that. Just count in 7, I'm not sure it's	14 15 16 17 18 19 20 21	Q Yeah, he's A We're on page 7? Q Yeah. Where is Sathyanar MR. O'CONNOR: What report are we looking at again? MS. DALY: The April one. THE WITNESS: Supplementary report, April 7.
14 15 16 17 18 19 20 21 22	A Yes. Correct. Q Okay. And if you would look at that again. I forget what we've numbered that. A Oh, do I still have it? Yes, I do. Q Is it there? A Yes. No. 12. Q Okay. 12. If you look at Table 4 on page 7 of that. Just count in 7, I'm not sure it's actually 7. Table 4.	14 15 16 17 18 19 20 21 22	Q Yeah, he's A We're on page 7? Q Yeah. Where is Sathyanar MR. O'CONNOR: What report are we looking at again? MS. DALY: The April one. THE WITNESS: Supplementary report, April 7. BY MS. DALY:

	In Re: Bard IVC Filt		• .
	Page 154		Page 156
1	Q Oh, I see it.	1	filter at implantation." I don't know if it's a
2	A Yeah.	2	comment about it later on as well.
3	Q Yep.	3	Q Yeah
4	A Yes.	4	A And
5	Q Okay. So you cited to that page that	5	Q I didn't see anything about him
6	paper that detected an arm fracture in a Denali 13	6	noticing
7	months after implant?	7	A Yeah.
8	A Correct.	8	Q any other complication in connection
9	Q And then you cited to Majdalanay on two	9	with that fracture.
10	other Denali fractures?	10	A Right. Right.
11	A Correct.	11	Q Okay.
12	Q And he was reporting on some fractures	12	A But I would comment that what that
13	that he had found in the raw database?	13	statement must mean is that if there was any tilt,
14	A That's correct.	14	it was very small.
15	Q First of all, you don't know whether the	15	Q Okay. And the reason that you cited to
16	paper that he's counting the stuff from Majdalanay,		these papers in your Denali section was to note
17	whether that included the previous reports of	17	that Denali can fracture?
18	Denali fracture from Kuo and Sathyanarayana?	18	A Yes, that's correct.
19	A No, I don't know.	19	Q Okay. Let's talk about your water hammer
20	Q Okay. Now, the Kuo and Sathyanarayana	20	effect
21	reports do not state whether the filter was tilted,	21	A Okay.
22	perforated or migrated before fracture, do they?	22	Q issue for a moment. And that relates
23	A I don't exactly recall, but I didn't write	23 24	to potential leg fractures, as I understand it,
24 25	it down so I I'm assuming that that's the case.	25	with clot hitting them?  A That's correct.
23	Q Okay.	23	
1	Page 155  A I would have written it down if I observed	1	Page 157 Q All right. And I think you talk about
2	that in the papers.	2	this at page 9 of your other report, your big
3	Q And the Majdalanay reported that both	3	report.
4	patients he saw with a filter a Denali fracture	4	A Page 9?
5	had center filters and there was no comment about	5	Q Of the main report. Yeah.
6	perforation or migration. Let me show you that.	6	A Oh, you mean in the summary. I see.
7	We'll mark that as and I'm happy to	7	Q Yeah, in the March report. I think it's
8	show you the other ones, too, if you'd like. This	8	at page 9. We're going way backwards.
9	is 16, Majdalanay.	9	MR. O'CONNOR: Which report?
10	(Whereupon, Deposition Exhibit 16 was	10	MS. DALY: His original March 17 report,
11	marked for identification by the Court	11	at in paragraph 4 on page 9.
12	Reporter.)	12	THE WITNESS: Correct.
13	THE WITNESS: You've given me two copies	13	BY MS. DALY:
14	of something.	14	Q Okay. Now, what analysis have you done to
15	BY MS. DALY:	15	quantify well, to ascertain that this water
16	Q Okay. Give me that back,	16	hammer effect, as you describe it, occurs?
17	Am I right, that	17	A Well, can I make one comment, first of
18	A Oh.	18	all, which is that I interpret this water hammer
19	Q he reports that they were centered?	19	effect to encompass the arrival of a blood clot
20	A Well, the wording I find the centering	20	that simply pushes the filter because of its
21	wording may be elsewhere, but it's the wording I	21	arrival. In other words, there's something driving
22	found, this is the Madja Majdalanay paper	22	the blood clot, there's the clot arrives at the
23	Q Uh-huh,	23	filter and it has to push the legs to make room for
		24	itself as it inserts itself into the filter.
24	A it says "No filter tilt or angulation	24	usen as a miser's asen into the inter.

40 (Pages 154 - 157)

			T. 440
1 1	Page 158	١.	Page 160
1 2	hammering, does it?	1 2	in this litigation where the patient had an occlusion?
2	A Well, no, it may not hammering may not	2	***************************************
3	be the right wording to use in terms of implied	3	A I'm not aware of that.
4	severity, but it is possible, because of the	4	Q Okay. And do you know how often an
5	pulsatile flow, for that blood clot to continue to	5	occluded Bard IVC filter occurs?
6	push multiple times on on the clot sorry, on	6	A I don't know.
7	the filter.	7	Q Okay. All right. Would would the
8	Now, there's there's another model that	8	water hammer effect, if it occurs, lead to fracture
9	I discuss which is perhaps more clearly the water	9	in your view or one of the other complications?
10	hammer effect, which is what you get in pipes in	10	A Well, it's going to contribute to
11	houses when you hear banging in the in the	11	fracture, although it may dislodge the filter and,
12	pipes, where you shut a faucet off and the motion	12	therefore, cause it to migrate, or it could distort
13	of the water is arrested very suddenly and that	13	the filter so much that it either is able to tilt
14	generates a very high pressure that impinges on the		or it may not even function well as a clot traffic
15	valve that you've just closed. And that is another	15	device. So although I so there are other
16	aspect of the situation that I'm including in my	16	possible consequences to the effect of the water
17	broad meaning of the water hammer effect.	17	hammer event.
18	Q And to analyze this what we've called	18	Q Let's talk about tilt for a minute.
19	water hammer effect, that's really a dynamic	19	A Yes.
20	condition?	20	Q If you go back to your March report, it's
21	A Yes, it is.	21	in your big report, at page 10, the first thing you
22	Q Okay.	22	talk about there is very top of the page, paragraph
23	A Yes.	23	5.
24	Q Did you do an analysis with a dynamic	24	A Yes.
25	analysis of that potential condition?	25	Q "The filter is unstable after
	Page 159		Page 161
1	MR. O'CONNOR: Form.	1	implementation in the vena cava, and it is very
2	THE WITNESS: Well, that's what my water	١ ^	
		2	likely that it will always tilt."
3	hammer analysis is, that it's based on fluid moving	3	likely that it will always tilt."  A Correct.
3 4		l	•
1	hammer analysis is, that it's based on fluid moving	3	A Correct.
4	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.	3 4	A Correct. Q To which Bard filters does this opinion
4 5	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava. BY MS. DALY:	3 4 5	A Correct. Q To which Bard filters does this opinion apply?
5 6	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.	3 4 5 6	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I
4 5 6 7	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly	3 4 5 6 7	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise
4 5 6 7 8	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of	3 4 5 6 7 8	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer?
4 5 6 7 8 9	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a	3 4 5 6 7 8 9	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course.
4 5 6 7 8 9	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.	3 4 5 6 7 8 9	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them.
4 5 6 7 8 9 10	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the	3 4 5 6 7 8 9 10	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like
4 5 6 7 8 9 10 11 12	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this	3 4 5 6 7 8 9 10 11	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali?
4 5 6 7 8 9 10 11 12 13	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this effect?	3 4 5 6 7 8 9 10 11 12	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali? A Yes.
4 5 6 7 8 9 10 11 12 13 14	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this effect?  A It — it would have to occlude the filter.	3 4 5 6 7 8 9 10 11 12 13	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali? A Yes. Q How much tilt are you talking about when
4 5 6 7 8 9 10 11 12 13 14 15	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this effect?  A It — it would have to occlude the filter.  Q Okay. It would have to occlude?	3 4 5 6 7 8 9 10 11 12 13 14 15	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali? A Yes. Q How much tilt are you talking about when you say they will always tilt?
4 5 6 7 8 9 10 11 12 13 14 15	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this effect?  A It — it would have to occlude the filter.  Q Okay. It would have to occlude?  A Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15 16	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali? A Yes. Q How much tilt are you talking about when you say they will always tilt? A A small amount. Measured by 1 or 2 or 3
4 5 6 7 8 9 10 11 12 13 14 15 16 17	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this effect?  A It — it would have to occlude the filter.  Q Okay. It would have to occlude?  A Yes.  Q All right. And then what you've got,	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali? A Yes. Q How much tilt are you talking about when you say they will always tilt? A A small amount. Measured by 1 or 2 or 3 degrees.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this effect?  A It — it would have to occlude the filter.  Q Okay. It would have to occlude?  A Yes.  Q All right. And then what you've got, going back to your — your plumbing example, you	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali? A Yes. Q How much tilt are you talking about when you say they will always tilt? A A small amount. Measured by 1 or 2 or 3 degrees. Q Okay. Do you know if there's any clinical
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this effect?  A It — it would have to occlude the filter.  Q Okay. It would have to occlude?  A Yes.  Q All right. And then what you've got, going back to your — your plumbing example, you got so much of a hair clot in your plumbing that	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali? A Yes. Q How much tilt are you talking about when you say they will always tilt? A A small amount. Measured by 1 or 2 or 3 degrees. Q Okay. Do you know if there's any clinical significance to a 1 to 3 percent 1 to 3 degree
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	hammer analysis is, that it's based on fluid moving in a — in a what I will call a vena cava.  BY MS. DALY:  Q Okay.  A It's a — it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.  Q So do you — do you — do you assume the size of the clot that's necessary to have this effect?  A It — it would have to occlude the filter.  Q Okay. It would have to occlude?  A Yes.  Q All right. And then what you've got, going back to your — your plumbing example, you got so much of a hair clot in your plumbing that you have really no water coming past?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A Correct. Q To which Bard filters does this opinion apply? A Well, it applies specifically to the I think it's the G2 that I did no, can I revise that answer? Q Yeah. Of course. A It applies to all of them. Q Okay. Even the ones with anchors, like Meridian and Denali? A Yes. Q How much tilt are you talking about when you say they will always tilt? A A small amount. Measured by 1 or 2 or 3 degrees. Q Okay. Do you know if there's any clinical significance to a 1 to 3 percent 1 to 3 degree tilt of an IVC filter?
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	In Re: Bard IVC Filt	~ C 1 2 1	10ddolo Bidoliity
	Page 162		Page 164
1	determine what a tilt in the amount of 1 to 3	1	THE WITNESS: Well, I think there's
2	degrees might do to contribute to strains or	2	could you repeat the question.
3	loading on the filter?	3	BY MS. DALY:
4	A Yes. I I used an estimate based on the	4	Q Yeah.
5	angle of tilt to calculate what tilt can do to the	5	So what I'm trying to figure out is have
6	level of strains involved, and it's proportional	6	you done an analysis that looks at "I'm going to
7	not directly proportional but the bigger the tilt,	7	start at 5 degrees of tilt," let's just say, "and
8	the bigger the effect.	8	I've analyzed it, I've done modeling that tells me
9	Q And which effect is the tilt going to	9	that 5 percent" "5 degrees of tilt to the left,
10	what is the tilt going to effectuate, first of all?	10	you will see strains in X, Y, Z places in the
11	A It's going to it's going to raise what	11	filter of"
12	are called the alternating strains that contribute	12	A So
13	to fracture.	13	Q "a certain amount"?
14	Q How about perforation, does it how does	14	A you're asking me about the strains that
15	it relate to that?	15	contribute to fatigue.
16	A I it's my assessment that a small	16	Q Sure.
17	amount of tilt will set off an asymmetric response	17	A Okay. So I did a calculation and I recall
18	of the of the filter and can lead to tilt	18	that the angle of tilt I assumed was 45 degrees, so
19	occurring, because because the	19	that's the only direct calculation that I've done.
20	Q Tilt or	20	But the formula involved can be used to compute the
21	A Sorry, what was the question?	21	strains that would be associated with any level of
22	Q More tilt?	22	tilt, including much smaller values.
23	A Sorry, what was the question? Oh, sorry,	23	Q To bring about fatigue?
24	yeah, I misstated my answer.	24	A To bring about fatigue.
25	Q Yeah.	25	Q So then let's back up and I'm going to ask
	Page 163		Page 165
1	A Sorry. So it is my assessment, from the	1	you the question. Have you done the same kind of
2	mechanics, that a small amount of tilt will	2	meddling modeling, not meddling modeling, to
3	generate an asymmetric loading in the sense that	3	look at any certain degrees of tilt and be able to
4	one of the arms will apply a bigger force to the	4	tell us what force that puts on struts that would
5	wall of the vena cava than other ones, which will	5	contribute to perforation, for example?
6	generate more tendency for it to perforate the vena	6	MR. O'CONNOR: Object to the form.
7	cava wall, and then that can ultimately contribute	7	THE WITNESS: I haven't done any numerical
8	to tilting occurring.	8	calculations regarding that.
9	Q And what what low amount of tilt have	9	BY MS. DALY:
10	you analyzed in reaching your conclusion that a low	10	Q You've basically done a deduction, you
11	degree of tilt will set that in process?	11	deduced that?
12	A I haven't analyzed any level of tilt in	12	A Exactly.
13	that sense.	13	Q All right.
14	Q Okay.	14	A Although I should comment that Dr. Briant
15	A I've simply used the deduction that the	15	does a calculation in which he looks at the loads
16	loads on the legs will not be the same and,	16	applied by the feet filters that have tilted and
17	therefore, one of them is going to it's likely	17	finds that in the tilted filter the loads applied
18	that one of them will the one that's more	18	by the one of the at least one of the limbs
19	heavily loaded will perforate the wall of the vena	19	of the tilted filter is higher than the loads
20	cava more rapidly than the one that's lightly	20	applied in the case of the untilted filter.
21	loaded.	21	Q But how that then contributes to
22	Q But to model that, a 5 degree tilt to the	22	occurrence of perforation or progressive of
23	left will add X amount of strain to struts on the	23	perforation, you haven't looked at that?
24	left or the right, you have not done that?	24	A I haven't looked
25	MR. O'CONNOR: Form.	25	MR. O'CONNOR: Form.
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	In Re: Bard IVC Filt	C12 T	Toducts Liability
	Page 166		Page 168
1	THE WITNESS: directly at it, but it's	1	the cases that you've seen in this litigation and
2	my assessment the higher the loads, the more likely	2	medical literature and other things, that there's a
3	perforation is to occur and the more rapidly it is	3	range?
4	likely to occur.	4	A That's correct.
5	BY MS. DALY:	5	MR. O'CONNOR: Form.
6	Q And I have to ask this question for my	6	BY MS. DALY:
7	record, but you've developed no test to bench test	7	Q Okay. So have you done any analysis to
8	that deduction or hypothesis, that certain degrees	8	determine what percentage of people with Bard
9	of tilt will cause perforation in certain places to	9	filters have conditions that meet your assumptions?
10	certain degrees, right?	10	A Oh, is that the question?
11	MR. O'CONNOR: Form.	11	Q Yeah. Is it 1 percent? 99 percent?
12	THE WITNESS: I've I've developed no	12	A I have done no such study.
13	test to test that hypothesis or that theory. I	13	Q Okay. So you don't know?
14	would I only point to the prevalence of the	14	A I don't know.
15	behavior in regard to other implants and other	15	Q And have you found in the cases you've
16	tissues that is a common observation.	16	looked at and the work you've done whether there's
17	BY MS. DALY:	17	any predictability of failures in any particular
18	Q All right. Let's look at your March	18	type of person, type of situation?
19	report, page 13, the paragraph just above the 4.2	19	A Well, I'm always looking at worst-case
20	section.	20	conditions, and so the question of predictability
21	A Yes.	21	is really not the point to be made but, rather,
22	Q And it says "A conclusion that can be	22	that having identified worst-case conditions, that
23	drawn from the above," we'll get there in a minute,	23	will those worst-case conditions, are they are
24	"is that the likelihood of fracture due to fatigue	24	they probable in terms of causing failures of the
25	in the Bard G2 filter is patient-dependent and can	25	filter. And, therefore, I've not looked at how
	Page 167		Page 169
1	be influenced by the details of how a normal	1	quickly are the rates at which these negative
2	successful implantation occurred with some patients	2	consequences will occur.
3	having an experience in which their G2 filter	3	Q And have you have you looked to
4	offers no danger of fracture while other patients	4	determine or have found from medical experts or
5	are not so fortunate."	5	literature that there are in fact persons who
6	Would you explain to me what what you	6	with Bard filters who fall in the worst-case
7	mean.	7	scenario?
8	A Well, what I mean is that even that	8	MR. O'CONNOR: Form.
9	even if a filter is implanted in a successful	9	BY MS. DALY:
10	manner, and that's something that I would leave to	10	Q In other words, they're people that those
11	medical experts to to define, but what I'm	11	things are going on with?
12	saying is that the implantation itself does not	12	MR. O'CONNOR: Form
13	directly cause any complications, that there are	13	THE WITNESS: Well
14	features of the behavior, features of the - of the	14	MR. O'CONNOR: and foundation.
15	results, that can occur because of differences	15	THE WITNESS: Well, with Bard filters, no,
16	among patients just because of their different	16	I haven't made that assessment.
17	physiology, which is a range of of of	17	BY MS. DALY:
18	features that we've discussed already	18	Q Nor nor have you assessed what percent
19	Q Okay.	19	of people with Bard filters could fall into the
20	A that is is normally come across in	20	worst-case scenario?
21	populations of patients, and that some of those	21	A No.
22	physiologies, some of in some cases it will lead	22	MR. O'CONNOR: Object to the form.
23	to negative consequences and other cases it it	23	THE WITNESS: I haven't made that
24	can lead to situations which are quite benign.	24	assessment.
25	Q And that's what we've seen in looking at	25	MS. DALY: What time is it?

	In Re: Bard IVC Filt	CI 5 I	Toducts Liability
	Page 170	١.	Page 172
1	12:45 1 MR. O'CONNOR: .	1	likely.
2 2	MS. DALY: Do you want to eat something?	2	A Well, the the size of the vena cava I
3 3	THE WITNESS: Might as well have some	3	expect play a role because the smaller the vena
4 4	lunch.	4	cava, the bigger the force that the filter will
5 5	MS. DALY: Yeah. Why don't we stop a	5	apply to the walls of the vena cava. There are
6 6	minute and have lunch. We're making let's go	6	other aspects of the attributes of the tissue in
7 7	off the record.	7	the vena cava wall that I would expect to play a
8 8	THE VIDEOGRAPHER: This is the end of	8	role in determining whether or how much perforation
9 9	Media No. 2. We are going off the record at 12:46.	9	will take place, and those are to do with just the
10 10	(Lunch recess taken.)	10	properties of of the of the tissue.
11 11	THE VIDEOGRAPHER: This is the beginning		Q Have you read any medical literature
12 12	of Media No. 3. We are back on the record at 1349.	12	identifying any types of people in patient
13 13	BY MS. DALY:	13	populations that are more susceptible to
14 14	Q Dr. McMeeking, let's talk about	14	perforation than others?
15 15	perforation for a minute.	15	A I believe I have, but I don't recall
16 16	A Okay.	16	exactly the details of that situation.
17 17	Q Can you summarize what what are the	17	Q And you have taken no data from that type
18 18	causes of perforation in the Bard filter that	18	of literature to try to analyze it or do any
19 19	you're aware of?	19	modeling with it; is that right?
20 20	A Well, I covered that in my report so so	20	A That no, I haven't done that, because
21 21	there are sections where I look at the issue of	21	what's most important is the observation that the
22 22	what would drive perforation, and those issues are	22	limbs of the Bard filters do perforate the wall of
23 23	the force that the leg applies to the wall of the	23	the vena cava.
24 24	vena cava and the size of the of the of the	24	Q Do you hold the opinion that Bard filters
25 25	limb because that controls the pressure that the	25	perforate more than any other IVC filters on the
	Page 171		Page 173
1 li	imb will apply against the vena cava wall. And	1	market?
2 tl	hat's covered in my report.	2	A I I don't have that opinion. I mean, I
3	Q Is there any difference in contribution to	3	don't have any opinion on that one way or the
4 p	erforation between arms and legs or in mechanisms	4	other.
5 b	by which they do it?	5	Q All right. Now, we've talked several
6	A Well, the mechanisms are the same, and as	6	times already this morning about some of your
	think I say in my report, the force that the arms	7	criticisms of Bard's testing of filters, correct?
	pply to the wall of the vena cava are greater than	8	A Correct.
9 tl	he forces that the legs apply, and, therefore,	9	Q All right. Have you determined, with
	epending on the extent of the area of contact, it	10	respect to any of Bard's testing that you're
	s likely that the arms will perforate the wall of	11	critical of, that had Bard tested with different
	he vena cava to a greater extent than the legs,	12	protocols, the test results would have revealed
13 a	lthough I expect both the legs and the arms to	13	something different?
14 p	erforate the wall of the vena cava.	14	MR. O'CONNOR: Form.
15	Q Did you determine any catient	15	THE WITNESS: I'm not quite sure what you
16 p	atient-specific conditions that would make a	16	mean by have I done anything to determine that, but
17 p	articular that would make a particular patient	17	what I've done is that I've identified the nature
18 m	nore or less susceptible to perforation?	18	of tests that would be more revealing of the
19	A Can you clarify that question. What	19	performance of of the filter and, therefore,
20 w	vhat	20	would be more informative than the tests that Bard
21	Q Yeah.	21	did on the filters that they were intending to
22	A What contributions are you thinking of?	22	to market.
23	Q In anything that you have identified that	23	BY MS. DALY:
24 y	ou think impacts whether a particular individual	24	Q And then beyond that, have you taken any
-	vill be more likely to have perforation or less	25	step to verify that those different tests would in
	<u> </u>		· · · · · · · · · · · · · · · · · · ·

1 fact show you something different more 2 A Well, I haven't done any tests but I've 3 considered the mechanics of what would occur in the 4 tests, and that leads me to conclude that there 5 would be you would expect to see significant or 6 at least substantial differences between the 7 behavior in the tests that I've been thinking of 8 and the ones that were actually carried out. 9 Q But as an engineer, you have seen 10 occasions where testing results actually surprised 11 you, that they didn't meet the hypothesis, true? 12 MR. O'CONNOR: Object to the form of the 13 question. 14 THE WITNESS: That does happen from time 15 to time, but of course the steps that one would 16 take then are either to consider whether the tests 17 need to be redesigned or whether the hypothesis 18 needs to be modified so 19 BY MS. DALY: 10 Q Right. 21 A there's a step forward that needs to be 22 taken. And I don't think Bard took those steps 23 based on their observations of what was happening 24 to the filter. 25 Q And you haven't taken those steps forward 27 the situation. 28 Q Okay. You're not going to give opinions on your interpretation of medical literature that reports on various incidents of complications of is that correct?  A I'm not going to give opinions on your interpretation of medical literature that reports on various incidents of complications of is that correct?  A I'm not going to give opinions on your interpretation of medical literature that reports on various incidents of complications of is that correct?  A I'm not going to give opinions on what's in the medical literature, other than to say that they're consistent with my assessment of the engineering considerations of the filters and that they're consistent with my assessment of the engineering considerations of the filters and that they're consistent with my assessment of the engineering considerations of the filters and that they're consistent with my assessment of the engineering considerations of the filters and that they're consistent with my	_	III KC. Dald IV C FII		<u>-</u>
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4 tests, and that leads me to conclude that there 5 would be — you would expect to see significant or 6 at least substantial differences between the 7 behavior in the tests that I've been thinking of 8 and the ones that were actually carried out. 9 Q But as an engineer, you have seen 10 occasions where testing results actually surprised 11 you, that they didn't meet the hypothesis, true? 12 MR. O'CONNOR: Object to the form of the 13 question. 14 THE WITNESS: That does happen from time 15 to time, but of course the steps that one would 16 take then are either to consider whether the tests 17 need to be modified so — 18 PMS. DALY: 19 BY MS. DALY: 20 Q Right. 21 A — there's a step forward that needs to be 22 taken. And I don't think Bard took those steps 23 based on their observations of what was happening 24 to the filter. 25 Q And you haven't taken those steps forward 26 regulations relating to testing that Bard failed to 7 meet? 27 A No, I have not. 3 MR. O'CONNOR: Form. 4 BY MS. DALY: 5 Q Okay. Are you aware of any FDA 6 regulations relating to testing that Bard failed to 7 meet? 9 THE WITNESS: I'm — I'm not giving any 10 opinion on what they did relative to requirements 15 G and I'm and it is a provide an opinion that 15 Bard had a higher rate of any particular type of 16 complication relative to other filters? 17 MR. O'CONNOR: Form. 18 WMS. DALY: 19 All right. Thank you. 19 Are you going to provide an opinion that 19 Are you going to provide an opinion that 10 the medical literature, other than to say that they re consistent with my assessment of the engineering considerations of the filter and that they reconsistent with my assessment of the engineering considerations of the filter and that they tend to confirm that the filters are — have — are dangerous. 20 Q Well, let's talk about that a minute. 21 What you — what you would take from medical literature is that there are reports of, for example, fracture, pher and that they reconsistent with my assessment of the engineering considerations of the filter and		•		
5 would be you would expect to see significant or 6 at least substantial differences between the 5 behavior in the tests that I've been thinking of 8 and the ones that were actually carried out. 9 Q But as an engineer, you have seen 10 occasions where testing results actually surprised 11 you, that they didn't meet the hypothesis, true? 12 MR. O'CONNOR: Object to the form of the 13 question. 14 THE WITNESS: That does happen from time 15 to time, but of course the steps that one would 16 take then are either to consider whether the tests 17 need to be redesigned or whether the thypothesis 18 needs to be modified so 19 BY MS. DALY: 19 Saed on their observations of what was happening 19 to the filter. 19 Q And you haven't taken those steps 19 Q O Ray. Are you aware of any FDA 19 G O Ray. Are you aware of any FDA 10 opinion on what they did relative to requirements 10 of the FDA. 12 BY MS. DALY: 13 Bard had a higher rate of any particular type of complication relative to other filters? 14 MR. O'CONNOR: Form. 15 Bard had a higher rate of any particular type of complication relative to other filters? 16 MR. O'CONNOR: Form. 18 Would be word that these significant or the medical literature, other than to say that they're consistent with my assessment of the engineering considerations of the filter and that they're consistent with my assessment of the engineering considerations of the filter and that they're consistent with my assessment of the engineering considerations of the filter and that they're consistent with my assessment of the engineering considerations of the filter and that they're consistent with my assessment of the engineering considerations of the filter and that they're consistent with my assessment of the engineering considerations of the filter and that they're consistent with my assessment of the engineering considerations of the filter and that they're consistent with my assessment of the engineering considerations of the filter and that they're consistent with my assessment of the engineerin	1		1	
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17 MR. O'CONNOR: Form. 17 Q Yeah. 18 THE WITNESS: I'm not going to offer any 18 You used the word that they that these	1			•
18 THE WITNESS: I'm not going to offer any 18 You used the word that they that these	1			
, , , , , , , , , , , , , , , , , , ,	1			
				symptoms. Isn't it more correct to say they can,
21 BY MS. DALY: 21 they don't always?	1		1	
22 Q What about one Bard filter versus another 22 MR. O'CONNOR: Form.				
	1	•		THE WITNESS: They they can generate
24 A I'm not going to give an opinion on that 24 patient symptoms.				, , ,
, , , , , , , , , , , , , , , , , , , ,	25	because I don't have enough data to truly assess	25	BY MS. DALY:

	Page 178	1	Page 180
1	Q And you've seen literature that reports	1	his report; for example, he'll he's got some
2	that they can be asymptomatic, true?	2	medical literature in here that he just told me he
3	A I'm aware of that literature, too.	3	doesn't really rely on, it has to do with rates and
4	Q Okay. Is there any medical literature	4	stuff, so
5	that we have not discussed thus far today that you	5	MR. O'CONNOR: Well, I
6	rely on for any of your opinions in the case	6	MS. DALY: I don't think we're missing.
7	directly? And there's one that's sitting in front	7	(Whereupon, Deposition Exhibit 17 was
8	of us that we haven't talked about. It looks like	8	marked for identification by the Court
9	that's an engineering	9	Reporter.)
10	A Yeah	10	BY MS. DALY:
11	Q rather than	11	Q Here, this this that I've marked as
12	A that's the materials engineering paper.	12	Exhibit 17 has got Robertson, "A statistical
13	Yeah.	13	approach to understand the role of inclusions on
14	Q Okay. Any other medical literature that I	14	the fatigue resistance of superelastic nitinol wire
15	may have missed?	15	and tubing," published in 2015.
16	A Not literature in the sense of published	16	Could you tell me what that what you
17	papers, but of course there's the expert reports	17	rely on that for.
18	Q Right.	18	A Well, I rely on it because there are some
19	A in in the various cases.	19	experimental data in here that relate to the
20	Q And what do you rely on from any of the	20	fatigue properties of nitinol
21	expert reports that we haven't talked about thus	21	Q Okay.
22	far? I know what you've relied on from Richie.	22	A and specifically to nitinol wire. And
23	What other ones	23	the reason that I'm talking about it is that
24	A Well, from	24	Dr. Briant says that this paper shows that the
25	Q you've taken anything from?	25	fatigue limit for nitinol can be higher than the
	Page 179		Page 181
1	A From Dr. Hurst to Dr. Muehrcke, I rely on	1	difference between the upper plateau of the
2	observations of what happened to the filter in	2	transformation stress strain curve and the lower
3	terms of of complications and negative events	3	plateau of the transformation stress strain curve,
4	that took place, such as fracture, tilt,	4	and I studied this paper and looked at the data and
5	perforation and migration.	5	there's two things that I should say about it.
6	Q And are you talking about the ones that	6	One is that the data on nitinol tubes that
7	they submitted in the Bellwether cases?	7	are turned into what is called a diamond specimen,
8	A Yes, that's correct.	8	those experiment and the experiments are done in
9	Q Okay. And we'll get to that.	9	those diamond-shaped specimens, those experiments
10	Anything else?	10	have to be interpreted through calculations, and,
11	A No, not that I can recall.	11	therefore, it's quite uncertain in regard to the
12	Q Okay. So while I remembered this document	12	accuracy of the results that are presented as a
13	lying in the middle of the table, let's talk about	13	consequence of the calculations which are carried
14	this and what this relates to vis-a-vis your	14	out.
15	opinions. I'm marking	15	In other words, it's it's entirely
16			
1	MR. O'CONNOR: Let me just get a	16	feasible and I think likely that the calculations
17	clarification. Are you asking him about any	17	are giving a misleading result for what goes on in
18	clarification. Are you asking him about any literature or reports not mentioned in his reports	17 18	are giving a misleading result for what goes on in the strains that are experienced by the the
18 19	clarification. Are you asking him about any literature or reports not mentioned in his reports that he prepared here?	17 18 19	are giving a misleading result for what goes on in the strains that are experienced by the the specimen during the test.
18 19 20	clarification. Are you asking him about any literature or reports not mentioned in his reports that he prepared here?  MS. DALY: No, I'm asking him whether	17 18 19 20	are giving a misleading result for what goes on in the strains that are experienced by the the specimen during the test.  Q Whose calculations are misleading?
18 19 20 21	clarification. Are you asking him about any literature or reports not mentioned in his reports that he prepared here? MS. DALY: No, I'm asking him whether there's anything else that he relies on for his	17 18 19 20 21	are giving a misleading result for what goes on in the strains that are experienced by the the specimen during the test.  Q Whose calculations are misleading?  A These are calculations carried out by the
18 19 20 21 22	clarification. Are you asking him about any literature or reports not mentioned in his reports that he prepared here?  MS. DALY: No, I'm asking him whether there's anything else that he relies on for his analyses today.	17 18 19 20 21 22	are giving a misleading result for what goes on in the strains that are experienced by the the specimen during the test.  Q Whose calculations are misleading?  A These are calculations carried out by the individuals who are associated with doing the
18 19 20 21 22 23	clarification. Are you asking him about any literature or reports not mentioned in his reports that he prepared here? MS. DALY: No, I'm asking him whether there's anything else that he relies on for his analyses today. MR. O'CONNOR: Separate and apart from	17 18 19 20 21 22 23	are giving a misleading result for what goes on in the strains that are experienced by the the specimen during the test. Q Whose calculations are misleading? A These are calculations carried out by the individuals who are associated with doing the experiments.
18 19 20 21 22	clarification. Are you asking him about any literature or reports not mentioned in his reports that he prepared here?  MS. DALY: No, I'm asking him whether there's anything else that he relies on for his analyses today.	17 18 19 20 21 22	are giving a misleading result for what goes on in the strains that are experienced by the the specimen during the test.  Q Whose calculations are misleading?  A These are calculations carried out by the individuals who are associated with doing the

	In Re: Bard IVC Filt	CI 3 I	
	Page 182		Page 184
1	Q he's talking about that?	1	triggering incremental transformation from
2	A Yeah, Robertson	2	austenite to martensite and then incremental
3	Q Oh.	3	transformation from martensite to austenite, that
4	A Robertson carries out some of those	4	the fatigue limit will be will be such that
5	calculations for the data in the experiment with	5	relatively rapid fatigue failure will occur if you
6	results such as Figure 3, illustrated, and uses	6	go above that level of strain.
7	those results to interpret the experiments which	7	Q And what you've pointed out about the
8	are carried out on specimens of a similar shape.	8	Robertson paper is that there are other situations
9	And what I'm saying is that those data are, in my	9	in engineering when direct testing on the bench of
10	view, unreliable because the results can be the	10	a device, a product, a material, gets you better
11	results as presented can be erroneous because of	11	real-life answers than doing your calculations,
12	errors in the calculations. The	12	doesn't it?
13	Q Okay. So	13	MR. O'CONNOR: Form.
14	MR. O'CONNOR: Hold it. Let him	14	THE WITNESS: Well, that's no, I
15	THE WITNESS: therefore, the only	15	don't I don't agree with that point of view,
16	reliable data, in my view, in this paper is the	16	because although it gives you certain answers
17	data obtained by carrying out experiments on wire,	17	related to the behavior of the component itself, it
18	which is under what is called tension tension; in	18	doesn't give you clean and direct information about
19	other words, you take the wire and you stretch it	19	the nature of the material, which is what you
20	and then you let it unstretch, and you do that	20	ultimately need to truly understand what is
21	repeatedly to obtain the fatigue data that you need	21	happening in the component that you're designing or
22	for the behavior of the material.	22	constructing or or testing.
23	And because the specimen is very simple,	23	BY MS. DALY:
24	just a wire that's straight and has a round	24	
25	cross-section, the results that you can get from	25	Q Do you know of any medical device
23	<u> </u>	23	manufacturer that puts a device on the market based
_	Page 183	_	Page 185
l	the tests are very reliable in the sense of knowing	I	on FE FEA work alone without bench testing?
2	exactly what the strains are during the test?	2	A I I know of no manufacturer who does
3	BY MS. DALY:	3	that.
4	Q Because that is a direct test of the	4	Q Do you know of any medical device that the
5	widget itself	5	FDA would clear without having some actual bench
6	A Correct.	6	testing?
7	Q of the material itself?	7	A I'm not familiar with what FDA does in
8	A Yes.	8	every particular case.
9	Q Okay.	9	Q Okay. Would you look at your March
10	A And and but most importantly, the	10	report, page 25. At the very bottom, paragraph 9.
11	calculations that you do to obtain the strain are	11	A Yes.
12	very simple and don't require assumptions about how	12	Q And it is a reference to an analysis by
13	to do calculations and what should go into those	13	biostatistician Rebecca Betensky?
14	those finite element calculations.	14	A That's correct.
15	So the data on the wire are clean, and	15	Q And then the last sentence on that page
16	when I look at the data on the wire, I find that	16	that goes on to page 26 is "Dr. Betensky's
17	the fatigue limit for the experiments that they're	17	analysis," and you cite to the report, "shows
18	doing is consistent with the difference in strain	18	statistically significant differences between the
19	between the upper plateau of the stress strain	19	Recovery and the Simon nitinol," et cetera.
20	transformation and the lower plateau, which is in	20	That that sentence then goes on, right?
21	contradiction to what Dr. Briant claims and	21	A Yes.
	supports my point of view that that if you	22	Q Okay. Have you read Dr. Betensky's
22			•
22 23	impose strain on the specimen which exceed the	23	report? Because you didn't mention that this
	impose strain on the specimen which exceed the difference between the upper plateau and the lower	23 24	report? Because you didn't mention that this morning. Maybe

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	In No. Data 1 V C 1 In	1	
١.	Page 186	1	Page 188
1	Q Did you read her report?	1	A No, I have not.
2	A I read it at the time that I wrote this	2	Q When you say at the top of page 26 that
3	report.	3	she found you have to go back to 25, that she
4	Q Okay. Did you review any of the actual	4	found statistically significant differences between
5	data that she analyzed?	5	the Recovery and the Simon nitinol filter and then
6	A I looked at tables and other information	6	between the Simon nitinol and the other Bard
7	in her reports. So in that sense I I reviewed	7	filters, what do you mean by "statistically
8	it.	8	significant differences"?
9	Q Her Excel sheets, did you	9	MR. O'CONNOR: Object to the form of the
10	A No, I didn't	10	question.
11	Q review her	11	THE WITNESS: That I mean that the
12	A No, I did not look at her Excel sheets.	12	differences in the numbers involved were put
13	Q Okay. Do you know what information her	13	through tests by her that analyzed the statistical
14	spreadsheets contain or don't contain with respect	14	distributions and the differences and the
15	to information about the Simon nitinol filter	15	comparisons and indicated, in the cases that I've
16	versus other Bard filters?	16	identified, that these these deductions made
17	A Well, I understand that the her Excel	17	from those statistics by her were meaningful in
18	sheets contain information about failures that were	18	that they were identifying real differences in the
19	identified in Bard and well, Bard filters and	19	performance and rates that were observed in the
20	that the source of some of that information was	20	various filters.
21	more data, and so on.	21	BY MS. DALY:
22	Q Do you know what time frames she had data		Q They were showing lower numbers of
23	for data from?	23	reported incidents of fracture in Simon nitinol
24	A I would need to look at her report to give	24	than the other filters?
25	you a specific answer to that.	25	A Yes, that's correct.
١.	Page 187		Page 189
1	Q Okay. If I tell you that she had data on	1	Q Okay. Was it just fracture that you were
2	the Simon nitinol from 2004, do you know that one		looking at or that that you rely on in any way
3	way or another?	3	in the report?
4	A I	4	A Well, the so there's statistical
5	MR. O'CONNOR: Form. THE WITNESS: I don't know that	5	differences among the filters compared to the Simon
6	information, but I could establish it by reviewing	6	nitinol and not just the fracture results but in
7 8	her report.	8	some other of the negative phenomena as well, but I would have to review the document to the report
9	BY MS. DALY:	9	to identify that explicitly.
10		10	Q And in what in what way does
11	Q Well, it that's fine.  You did not perform any of the biostat	11	Dr. Betensky's information support any conclusion
12	biostatistical calculations that went into her	12	that or opinion that you have in the case?
13	report, true?	13	MR. O'CONNOR: Form and foundation.
		14	THE WITNESS: Well, it it confirms and
14		7.4	AAD WILLIAMS. WOR, IL IL COMMINIS AND
14 15	A No, I yes, that's true, I did not carry	15	is consistent with my analysis confirms in the
15	out any of those calculations.	15 16	is consistent with my analysis, confirms in the
15 16	out any of those calculations.  Q And you did not independently verify her	16	sense that it's consistent with my analysis in that
15 16 17	out any of those calculations.  Q And you did not independently verify her work?	16 17	sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S and
15 16 17 18	out any of those calculations.  Q And you did not independently verify her work?  A No.	16 17 18	sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S and the Meridian, and to some extent the Denali, are
15 16 17 18 19	out any of those calculations.  Q And you did not independently verify her work?  A No.  Q Did you provide her with any information	16 17 18 19	sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S and the Meridian, and to some extent the Denali, are subject to rates of failure which are greater than
15 16 17 18 19 20	out any of those calculations.  Q And you did not independently verify her work?  A No.  Q Did you provide her with any information that she used in her report or that she	16 17 18 19 20	sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S and the Meridian, and to some extent the Denali, are subject to rates of failure which are greater than the Simon nitinol filter and that that is
15 16 17 18 19 20 21	out any of those calculations.  Q And you did not independently verify her work?  A No.  Q Did you provide her with any information that she used in her report or that she considered	16 17 18 19 20 21	sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S and the Meridian, and to some extent the Denali, are subject to rates of failure which are greater than the Simon nitinol filter and that that is consistent with my comparative assessment of the
15 16 17 18 19 20 21 22	out any of those calculations.  Q And you did not independently verify her work?  A No.  Q Did you provide her with any information that she used in her report or that she considered  A No	16 17 18 19 20 21 22	sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S and the Meridian, and to some extent the Denali, are subject to rates of failure which are greater than the Simon nitinol filter and that that is consistent with my comparative assessment of the Simon nitinol filter compared to the other filters
15 16 17 18 19 20 21 22 23	out any of those calculations.  Q And you did not independently verify her work?  A No.  Q Did you provide her with any information that she used in her report or that she considered  A No  Q as far as you know?	16 17 18 19 20 21 22 23	sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S and the Meridian, and to some extent the Denali, are subject to rates of failure which are greater than the Simon nitinol filter and that that is consistent with my comparative assessment of the Simon nitinol filter compared to the other filters in the Bard line of products.
15 16 17 18 19 20 21 22	out any of those calculations.  Q And you did not independently verify her work?  A No.  Q Did you provide her with any information that she used in her report or that she considered  A No	16 17 18 19 20 21 22	sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S and the Meridian, and to some extent the Denali, are subject to rates of failure which are greater than the Simon nitinol filter and that that is consistent with my comparative assessment of the Simon nitinol filter compared to the other filters

770.343.9696

Page 190  1 Simon nitinol just a minute.  2 Do you know who Dr. Thisted is?  3 A I — I understand that he is a  4 biostatistication at University of Chicago, but  5 that's all I know.  6 Q Okay. Have you read his report —  7 A I —  8 Q — that he did for Bard in this  9 litigation?  10 A I have not read that report.  11 Q Do you know what his opinions are about  12 Dr. Betensky's opinions?  13 A Since I haven't read the report, I don't  14 know.  15 Q Do you know that Dr. Betensky was  16 calculating — whether she was calculating risk  17 ratios or reporting risk ratios?  18 MR. O'CONNOR: Form.  19 MR. O'CONNOR: Form.  10 MR. O'CONNOR: Form.  11 PWITNESS: I would —  20 MR. O'CONNOR: Foundation.  21 THE WITNESS: I would head to review the 2 document to be sure which — which parameters she 22 was reporting.  24 By MS. DALY:  25 Q Do you know what the differences between  Page 191  1 those things are, a risk ratio and a reporting risk ratio?  3 A I'm not familiar with that difference.  4 Q Okay. Did Dr. Betensky do any work with respect to the probability of the occurrence of any complication in a Bard retrievable filter that you recall?  8 A Could you clarify that question.  9 Q Yeah.  Did she do any statistical analysis of the 11 probability, the likelihood, of which any complication would happen in any particular Bard retrievable filter?  10 MR. O'CONNOR: Form and foundation.  11 Probability, the likelihood, of which any complication would happen in any particular Bard retrievable filter?  12 A Could you clarify that question.  13 A Could you clarify that question.  14 MR. O'CONNOR: Form and foundation.  15 Q - or or how it compares —  16 A No.  17 A No.  18 A Could you clarify that question.  9 Q Yeah.  19 Did she do any statistical analysis of the 11 probability, the likelihood, of which any complication would happen in any particular Bard 12 Q.— or how be and filters?  18 A Could your clarify that question.  19 Q - or or how it compares —  10 Q - or or how it compares —  11 A No.  12 Q - to the Bard filters?	
2 Do you know who Dr. Thisted is? 3 A I I understand that he is a 4 biostatistician at University of Chicago, but 5 thats's all I know. 6 Q Okay. Have you read his report 7 A I 8 Q that he did for Bard in this 9 litigation? 10 A I have not read that report. 11 Q Do you know what his opinions are about 12 Dr. Betensky's opinions? 13 A Since I haven't read the report, I don't 14 know. 15 Q Do you know that Dr. Betensky was 16 calculating whether she was calculating risk 17 ratios or reporting risk ratios? 18 MR. O'CONNOR: Form. 19 THE WITNESS: I would 20 MR. O'CONNOR: Form. 21 THE WITNESS: I would need to review the 22 document to be sure which which parameters she 23 was reporting. 24 BY MS. DALY: 25 Q Do you know what the differences between  1 Thou that is all I know. 5 MS. DALY: 10 Do you know that Dr. Betensky was 11 (from you? 11 (from you? 12 (from you when did you get that? 13 (PONNOR: Hold on. 14 (from you? 15 (from you? 16 (from you? 17 (from a plaintiff's attorney, if he got it from an attorney? 26 Do you know what the differences between  17 Page 191  18 those things are, a risk ratio and a reporting risk ratio? 29 A I'm not familiar with that differences 20 Do you know what the difference of any complication in a Bard retrievable filter that you recall? 28 A Could you clarify that question. 29 Q Yeah. 20 Did she do any statistical analysis of the probability, the likelihood, of which any complication would happen in any particular Bard 13 retrievable filter? 20 The that's all X. Auc. 21 That'? 22 That's Dally: 23 Dally: Yeah, I want to know it friend, if he got it from a reporting risk remained by the document of the exemple remained by the friend, if he got it from an attorney? 22 A I received it from an attorney? 23 A I'm not fami	Page 192
3 A I—I understand that he is a 4 biostatistician at University of Chicago, but 5 that's all I know. 6 Q Okay. Have you read his report 7 A I 8 Q that he did for Bard in this 9 litigation? 10 A I have not read that report. 11 Q Do you know what his opinions are about 12 Dr. Betensky's opinions? 13 A Since I haven't read the report, I don't 14 know. 15 Q Do you know that Dr. Betensky was 16 calculating whether she was calculating risk 17 ratios or reporting risk ratios? 18 MR. O'CONNOR: Form. 19 THE WITNESS: I would 20 MR. O'CONNOR: Foundation. 11 THE WITNESS: I would 21 THE WITNESS: I would ed to review the document to be sure which which parameters she as was reporting. 24 BY MS. DALY: 25 Q Do you know what the differences between document to be sure which which parameters she as a risk ratio and a reporting risk ratio? 3 A I'm not familiar with that differences between document in a Bard retrievable filter that you receil? 4 A Could you clarify that question. 9 Q Yeah. 10 Did she do any statistical analysis of the probability, the likelihood, of which any complication would happen in any particular Bard retrievable filter?  3 A No.  3 MS. DALY: It's his rebuttal report, 1 11, 2017. 4 I1, 2017. 5 MR. O'CONNOR: Thank you. 6 BY MS. DALY: 9 Did you have the opportunity to ex exemplar Simon nitinol filter?  A I have a Simon nitinol filter?  A Last week.  Q Who sent it to you?  MR. O'CONNOR: He got it from I's somebody, but is that necessary to know?  MR. O'CONNOR: He got it from I's somebody, but is that necessary to know?  MR. O'CONNOR: Form a plaintiff's attorney, if he got it from an attorney?  A I received it from an attorney?  A I received it from an attorney?  A I received it from an attorney.  Q Okay. And you hade the appendance anything that you've written in the report about the SNF  A No.  Q Oyay. And you hade the opportunity to ex exemplar in mexaminatio	one is
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12 complication would happen in any particular Bard   12 Q to the Bard filters?   13 retrievable filter?   13 A No.	
13 retrievable filter? 13 A No.	
114 MR. O'CONNOR: Form and foundation.   14 O All right, You to do your rebutta	
l ' ' - '	
15 THE WITNESS: In an implanted 15 report, you looked at the engineering draw	ings for
16 BY MS. DALY:   16 the SNF	
17 Q Yes. 17 A Correct.	
18 A filter in a patient? 18 Q is that true?	
19 Q Yes. 19 A That's correct.	
20 A I would have to review the document to be 20 Q What else did you look at?	
21 sure, but I'm not aware of that analysis. 21 A I looked at well, I was looking at	the
22 Q All right. Let's talk about your SNF 22 510(k) for the Recovery	
23 analysis, which really comes in your rebuttal 23 Q Okay.	
24 report of 5-11-17, which we have marked as 24 A and it told me various things to do	
25 Exhibit 4. 25 with changes that were made, such as the c	liameter

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		1	
	Page 194		Page 196
1	of the of the limbs and the material of which	1	Bard's purpose in developing the Recovery filter
2	the filters were made, and so that enabled me to	2	was to provide for a filter that could be
3	draw conclusions about how to compare the Simon	3	percutaneously retrieved?
4	nitinol with the other filters.	4	A I understand that that's the case, but
5	Q Okay. And the Simon nitinol filter is	5	they were developing an optional filter which meant
6	basically got a round a rounded dome with	6	that it was represented as being usable as a
7	petals. You've got a good diagram of that at the	7	permanent filter as well as having the option of
8	back of the report. And then legs on the bottom,	8	being percutaneously removed.
9	six legs?	9	Q But so you do understand it had the
10	A That's correct, yes.	10	dual
11	Q Okay. What design characteristics of the	11	A I understand it has
12	Simon nitinol filter make that filt made that	12	Q the dual goals?
13	filter not retrievable percutaneously?	13	A that dual target.
14	MR. O'CONNOR: Form and foundation.	14	Q Right.
15	THE WITNESS: Well, I'm not entirely sure	15	And did you understand that an important
16	because I've not investigated that situation, but	16	benefit to patients in a retrievable IVC filter is
17	it's my surmise that it is the extent of of	17	the fact that it can be retrieved?
18	connection among the wire wires of the petals	18	A Well, I'm I'm not a doctor and I'm not
19	and the vena cava wall which presents more material	19	a medical expert so I don't know that in a detailed
20	that can bond from the vena cava wall to the petals	20	way, but from a position of someone who may be a
21	of the of the filter, and so that will generate	21	patient, it makes sense that one would want to have
22	a robust connection between the filter and the vena	22	the implant out if that is possible.
23	cava wall.	23	Q Okay. Now, in your in your rebuttal
24	BY MS. DALY:	24	report where you're comparing the Simon nitinol,
25	Q Did	25	you compare it to the G2 and Recovery filters,
	Page 195		Page 197
1	A And also the the legs do seem to	1	correct?

A And also the -- the legs do seem to perforate to some extent through the wall of the vena cava, and I -- I'm assuming that that would present complications upon retrieval. Q Did you investigate whether once deployed

that petal formation was at all difficult to slim back down, if you will, to crimp it into a sheath for retrieval? A Well, I made an estimate of the stiffness

of those petals, and so although I didn't make a comparison with what is required to put it into the delivery sheaths, I -- I did have the analysis at hand from which that could be undertaken.

Q And you determined they were pretty stiff?

15 They're -- they're

Q Not to use a good engineering term.

17 A Yeah, they're -- they're stiff compared to 18 the Bard arms -- sorry, the arms on the Recovery, 19 the G2, and other subsequent filters.

20 O And the legs are stiffer than the Recovery 21 and other retrievable --

22 A Yes.

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23 Q -- Bard filters as well?

24 A That's correct.

25 Q Okay. You understand that the -- that 2

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A Can you remind me of where I do that.

Q Yes. Let's see. Pages 8 through 16 is where you discuss the Simon nitinol. And if you look at the bottom of page 9, my impression is that you're looking at it comparatively to Recovery and G2 throughout and that you -- and that you didn't do specifically a head-to-head comparison of it to the later generations.

MR. O'CONNOR: Form.

THE WITNESS: I didn't do that specific comparison but that's because the characteristics of the later generations would be similar to the Recovery and the G2, and, therefore, at the level I was doing that comparison, it was not a significant aspect of what I needed to consider.

BY MS. DALY:

Q Okay. I understand that's your -- that's your opinion.

Okay. So what your -- what your report concludes about the SNF is a couple of things, and I'm trying to see whether I got this from a place where you summarized them all together or they're

All right. Let's start, first of all, on

50 (Pages 194 - 197)

	7. 100	1	
1	Page 198 page 9 at the second full paragraph where you say	1	Page 20 bushing, it goes out in a radial direction more or
2	"The shape of the petals." Do you see that?	2	less, there's a segment which is almost
3	A Oh, the second full paragraph.	3	circumferential in in regard to the shape of the
4	Q Yeah.	4	vena cava which by which I'm using to define
5	A I see it, yes, yes.	5	circumference.
6	Q "The shape of the petals is quite	6	Q Okay.
7	complicated, so to estimate their stiffness to	7	A And then the loop comes back in towards
8	radial compression I simply treat them as two arms		the center of the filter and enters the lower
9	of a length of 16 millimeters joined together."	9	bushing.
10	Okay. Will you explain to me what you	10	Q Okay.
11	mean by that. How did you do that analysis of	11	A So that's what I'm considering to be the
12	stiffness of the petalled shape?	12	loop.
13	A Well, I mean that I approximated them as	13	Q So for the first comparison that you did
14	straight wires that were in the form of a loop but	14	where the petal stiffness was 10 times that of a
15	the wires were the two wires sorry, I should	15	single arm of Recovery and 18 that of a single G2,
16	start again because I became imprecise.	16	are you able to take this yellow highlighter and
17	So I represented the petal as a single	17	draw for me what you were comparing off of the SNF
18	wire that has the shape of a loop but the loop is	18	against the Recovery or the G2 arm?
19	such that the two wires are parallel to each other	19	A I'm sorry, could you repeat that.
20	except at the end where they meet together in the	20	Q Yeah.
21	form of a of a junction adjoined, a joint.	21	I'm trying to figure out what you are
22	Q Okay. So so with that assumption, you	22	defining as the petal of the SNF where you say here
23	determined their basic stiffness?	23	on page 9 "A single petal of the SNF during radial
24	A That's correct.	24	compression is 10 times greater than that of a
25	Q Okay. Vis-a-vis the Recovery or the G2,	25	single arm of the Recovery and a single arm of the
23		23	
١.	Page 199	1	Page 20 G2."
1	you say that "The radial compression for the	1 2	A Okay. I'll do that by putting some
2	SNF" we're talking about the petal portion?	3	letters on the
3	A Yes.	4	Q Great.
4	Q Okay "is 10 times that of a single arm of Recovery and approximately 18 times that of	5	A diagram.
5 6	a single arm of the G2," right?	6	Q Perfect.
	· -	7	A A, B, C, D.
7	A Yes, that's what I that's what I wrote.	8	
8	Q But what you're comparing is the whole	9	
9	petal to one Recovery arm for comparison of	10	A And the is it going to be visible using yellow?
10	stiffness?	11	Q Well, you know what? You can have a per
11	A That's correct.		Do it any way that makes sense.
12	Q All right. So if you go down below that a	12	
13	couple more lines after you've talked about the 18	13	A So a single petal starts at A.  Q Okay.
14	times the single arm of the G2	14	· · · · · · · · · · · · · · · · · · ·
15	A Yes.	15	A Comes down to B.
16	Q you go down four lines and it says "I	16	Q Okay. A Runs around to C.
17	find that a single petal of the SNF is	17	
18	approximately 50 percent stiffer than a single arm	18	Q Oh, okay.
19	of the Recovery or G2."	19	A And then goes down into the other the
0.0	What what is the definition of the	20	lower bushing at D.
20	single petal?	21	Q All right.
21		22	
21 22	A Well, single petal is the loop that you	22	A So A, B, C, D is is that loop.
21 22 23	A Well, single petal is the loop that you can see in this diagram, although it's maybe	23	Q So it goes to the left of the cap and to
21 22	A Well, single petal is the loop that you		

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	Page 202		Page 204
1	Q All right. So when you mentioned single	1	I'm missing something.
2	petal a couple of sentences down, that's the same	2	The first one I wrote down was that it was
3	thing you're talking about where you say "A single	3	more resistant to migration than the Bard's
4	petal of the SNF is approximately 50 percent	4	retrievable filters. Is that a conclusion that you
5	stiffer"?	5	make?
6	A Yes.	6	A Yes, that's correct.
7	Q Okay. Then you say "If endothelialization	7	Q Okay. And in what direction is it more
8	constrains rotation of the wire where it's bonded	8	resistant to migration?
9	to the wall of the vena cava, all stiffness will	9	A Well, my engineering assessment would
10	increase by a factor of 4."	10	indicate that it's more resistant to migration
11	What do you mean by that?	11	after it's been firmly implanted in the vena cava,
12	A Well, I mean that if you have an end to	12	that it's more resistant to migration in both the
13	the loop or the Bard sorry, the G2 or Recovery	13	caudal and the cephalic direction.
14	arms and you compress it by the action that the	14	Q Okay. Are you saying that it will never
15	vena cava would apply to the filter as the	15	migrate?
16	reduction as the diameter of the vena cava	16	A No, I'm not saying that, no.
17	reduces, if you have an end of those features which	I .	Q Is it principally the stiffness of the
18	is capable of rotating as that deformation takes	18	petals that contributes to the migration resistance
19	place, you would get a certain value of the	19	in this or is it more than that?
20	stiffness where the stiffness is the ratio of the	20	A Well, I think it's I think it's a
21	force that you apply to the displacement which is	21	combination of the stiffness of the petals and the
22	imposed.	22	stiffness of the legs.
23	Q Okay.	23	Q Is there anything about any other
24	A Now if you constrain the rotation so that	24	dimensions of the Simon nitinol, diameter of wire,
25	the end both moves according to the vena cava wall		length of length of anything, height of the
	- · · · · · · · · · · · · · · · · · · ·		
_	Page 202	<b></b>	Page 205
1	Page 203	1	Page 205
1 2	but does not change its orientation relative to the	1 2	filter overall, anything like that, that
2	but does not change its orientation relative to the vena cava wall, then the stiffness will be four	2	filter overall, anything like that, that contributes to migration resistance?
2	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you	2	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls
2 3 4	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when	2 3 4	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that
2 3 4 5	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.	2 3 4 5	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has
2 3 4 5 6	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.  Q Okay. And that stiffness in the petal	2 3 4 5 6	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has an effect, which I've already alluded to in the
2 3 4 5 6 7	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.  Q Okay. And that stiffness in the petal area may make folding that back down, once it's in	2 3 4 5 6 7	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has an effect, which I've already alluded to in the in the answers I just gave.
2 3 4 5 6 7 8	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.  Q Okay. And that stiffness in the petal area may make folding that back down, once it's in the patient to put it in a sheath for retrieval,	2 3 4 5 6 7 8	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has an effect, which I've already alluded to in the in the answers I just gave.  Q Okay.
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2 3 4 5 6 7 8 9	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.  Q Okay. And that stiffness in the petal area may make folding that back down, once it's in the patient to put it in a sheath for retrieval, more difficult?  A It would mean	2 3 4 5 6 7 8 9	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has an effect, which I've already alluded to in the in the answers I just gave.  Q Okay.  A The length of the petals and the lengths of the legs also contribute to controlling the
2 3 4 5 6 7 8 9 10	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.  Q Okay. And that stiffness in the petal area may make folding that back down, once it's in the patient to put it in a sheath for retrieval, more difficult?  A It would mean MR. O'CONNOR: Form.	2 3 4 5 6 7 8 9	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has an effect, which I've already alluded to in the in the answers I just gave.  Q Okay.  A The length of the petals and the lengths of the legs also contribute to controlling the stiffness, so those would contribute as well. And
2 3 4 5 6 7 8 9 10 11 12	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.  Q Okay. And that stiffness in the petal area may make folding that back down, once it's in the patient to put it in a sheath for retrieval, more difficult?  A It would mean MR. O'CONNOR: Form. THE WITNESS: It would mean	2 3 4 5 6 7 8 9	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has an effect, which I've already alluded to in the in the answers I just gave.  Q Okay.  A The length of the petals and the lengths of the legs also contribute to controlling the stiffness, so those would contribute as well. And I'm not sure if I can identify anything else, but
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.  Q Okay. And that stiffness in the petal area may make folding that back down, once it's in the patient to put it in a sheath for retrieval, more difficult?  A It would mean MR. O'CONNOR: Form. THE WITNESS: It would mean MR. O'CONNOR: Foundation. THE WITNESS: It would mean that you have to pull on the filter with a bigger force relative to the Recovery catheter to put into that Recovery catheter.  BY MS. DALY: Q And what that might translate into insofar as patient injury, you do you have not done an analysis of that? A I have not done an analysis of that. Q All right. Now, this is what I wrote down	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has an effect, which I've already alluded to in the in the answers I just gave.  Q Okay.  A The length of the petals and the lengths of the legs also contribute to controlling the stiffness, so those would contribute as well. And I'm not sure if I can identify anything else, but those were those would be the things that I would identify.  Q Did you do any analysis of how one would make changes to either the petal dome or the legs of the SNF to allow it to be retrievable?  A Can I augment my answer of just a second ago? The the diameter or the span of the petals and the span of the arms the legs relative to the diameter of the vena cava would contribute to the forces which are involved and, therefore, contribute to the question of whether migration is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will that you apply will be four times that which you got when you did not constrain the rotation.  Q Okay. And that stiffness in the petal area may make folding that back down, once it's in the patient to put it in a sheath for retrieval, more difficult?  A It would mean  MR. O'CONNOR: Form.  THE WITNESS: It would mean  MR. O'CONNOR: Foundation.  THE WITNESS: It would mean that you have to pull on the filter with a bigger force relative to the Recovery catheter to put into that Recovery catheter.  BY MS. DALY:  Q And what that might translate into insofar as patient injury, you do you have not done an analysis of that?  A I have not done an analysis of that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	filter overall, anything like that, that contributes to migration resistance?  A Well, the diameter of the wire controls the stiffness of the wire of the components that are made from the wire, so that has a that has an effect, which I've already alluded to in the in the answers I just gave.  Q Okay.  A The length of the petals and the lengths of the legs also contribute to controlling the stiffness, so those would contribute as well. And I'm not sure if I can identify anything else, but those were those would be the things that I would identify.  Q Did you do any analysis of how one would make changes to either the petal dome or the legs of the SNF to allow it to be retrievable?  A Can I augment my answer of just a second ago? The the diameter or the span of the petals and the span of the arms the legs relative to the diameter of the vena cava would contribute to the forces which are involved and, therefore,

	— Mile. Baluit Cin	т —	
١.	Page 206	1	Page 20:
I	question, I didn't make do any analysis to look	1	Why don't you get the Poletti article and
2	at what changes might what changes what	2	take a look at it. Do we have it?
3	impact they would have on the behavior of the of	3	THE WITNESS: I don't have it.
4	the filter.	4	MR. O'CONNOR: Do you have
5	Q Including the last thing that you just	5	BY MS. DALY:
6	mentioned to me, the difference in span?	6	Q Do you agree that it says that? Do you
7	A Yes.	7	remember it saying that?
8	Q How that might have to be re-engineered to	8	A May I look may I look at the paper
9	allow for retrieval?	9	Q Of course.
10	A I did not look at that.	10	A to ascertain that?
11	Q Okay. The next thing that I saw from your	II	Q Of course. Let's make this 18.
12	report was that the design of the SNF legs make	12	(Whereupon, Deposition Exhibit 18 was
13	them more prone to perforation than the struts of	13	marked for identification by the Court
14	the Recovery and the G2?	14	Reporter.)
15	MR. O'CONNOR: Where are you looking at in	15	THE WITNESS: Thank you.
16	the report?	16	BY MS. DALY:
17	BY MS. DALY:	17	Q And if you look at the abstract, that
18	Q The different ones start on page 11. Your	18	might help you find it quickly.
19	first one was migration, and then the little B on	19	A In the abstract is it says "A CT
20	page 11 is where I'm reading from right now.	20	examination showed that the struts of the SNF have
21	I'm sorry, that's not where I got it from.	21	penetrated the vena cava in 95 percent."
22	Go to page 13. I apologize. B on page 13.	22	Q And then does it say something like
23	A Yes.	23	76 percent?
24	Q So I think what you concluded there was	24	A "And where in contact with adjacent
25	that the legs of the Simon nitinol were more prone	25	organs, in 76 percent."
	Page 207		Page 209
1	to perforation of the vena cava wall than the	1	Q Okay. All right. So is the in your
2	Recovery or G2?	2	analysis of the Simon nitinol, is the perforation
3	A In the legs of the Recovery and the G2.	3	of legs in the Simon nitinol related to the
4	Q The legs. Okay.	4	dimensions of the leg, the stiffness of the legs,
5	Did you look at any medical literature	5	or something else?
6	about the Simon nitinol to confirm whether you were	6	A Well, in my engineering assessment, it's a
7	correct that there was more that there was a	7	combination of of the stiff of the dimension
8	fair amount of perforation from the legs of the	8	of the leg or the length of the leg and the
9	Simon nitinol?	9	material from which it's made.
10	MR. O'CONNOR: Object to the form of the	10	Q So what would one have to do to engineer
11	question.	11	the legs of the Simon nitinol to diminish
12	THE WITNESS: I I didn't look at papers	12	perforation?
13	to specifically ascertain that information, but I	13	A One would perhaps lengthen the legs or
14	did read some papers that indicated that	14	make them smaller in diameter or one may choose a
15	perforation by the legs of the Simon nitinol filter	15	different material that is more compliant than the
16	do occur.	16	nitinol from which it's made.
17	BY MS. DALY:	17	Q Okay. But again, you have not tried to do
18	Q Are you familiar with the Poletti paper,	18	any finite element analysis or any testing to
19	for example, where he says that legs perforated	19	determine how one would re-engineer that, true?
20	95 percent of the time and 76 percent of the time	20	A I've done no calculations or tests
	to	21	Q Okay
21			F-100
21 22	A Yes, I	22	A in that regard.
	A Yes, I Q to organs?	23	Q The next one on page 14, C, is you're
22			

July 6, 2017

	In Re: Bard IVC Filt	ers I	Products Liability
	. Page 210		Page 212
1	tell me what your what you found.	1	Q Did you do any analysis of the Simon
2	A Well, as it as is written in the	2	nitinol for tilt and strains on the filter as a
3	report, the stiffness of the petals means that when	3	result of tilt as you did with the G2/Recovery
4	you compress them into a vena cava to achieve a	4	filters?
5	specific diameter of the petals, that the strain	5	A No, I did not carry out such calculations.
6	energy, the work that's stored in the petals, is	6	Q And the Poletti article talks about there
7	higher than the work that would be stored in the	7	being 63 percent of the Simon nitinols in that
8	arms of and the legs of the Recover yeah, the	8	study that demonstrated eccentric position. I
9	arms and the legs, and I should include the legs in	9	don't think that's in the abstract, I think I have
10	the Simon nitinol filter as well.	10	to go in there to look for it.
11	Q Okay.	11	A It is in the abstract.
12	A But the work done the work stored in	12	Q Okay.
13	the arms and the legs of the Simon nitinol filter	13	A It says "Filters were in eccentric
14	is greater than the work stored in the arms and	14	position in 63 percent."
15	legs of the Recovery and G2 filters where they've	15	Q And I take that to mean Poletti's talking
16	been put through the same reduction in size.	16	about tilt; is that what you think?
17	Q And what does that mean?	17	A I'm assuming that there was an
18	A It means that each component of the Simon	18	identifiable degree of tilt, so there was some tilt
19	nitinol filter has in other words, the petals or	19	and it was big enough that it could be identified.
20	the legs, has a higher driving force for tilting	20	Q Have you done any analysis comparing the
21	than the equivalent component of the Recovery and	21	Simon nitinol in whatever amount of tilt it could
22	the G2 filter.	22	do to how it would fare comparatively to the
23	Q Meaning it will tilt less or tilt more in	23	Meridian and Denali that have the anchors on them?
24	your opinion?	24	MR. O'CONNOR: Form.
25	A Well, it it each component will want	25	THE WITNESS: I haven't done such a
-	Page 211		Page 213
I	to tilt more but	1	comparative analysis except in the sense that it is
2	Q In the SNF or the	2	my assessment that the did you say the Meridian
3	A In the SNF.	3	and the Denali?
4	Q Okay.	4	BY MS. DALY:
5	A But there is a feature of the design of	5	Q Yes.
6	the SNF which is that you have these two bushings	6	A The Meridian and the Denali are very
7	with some compliance in between them which allows	7	similar in shape to the Recovery and G2, and,
8	the top of the filter to rotate relative to the	8	therefore, some of these features are analogous in
9	bottom, which means that that while there are	9	the Meridian and Denali in terms of the behavior in
10	high driving forces for the tendency to tilt, there	10	tilting.
11	is a more forgiving aspect to the filter that	11	Q But you haven't done any specific analysis
12	enables it to accommodate the tendency to tilt	12	to determine whether the modifications to the
13	perhaps by the petals alone tilting but not the	13	Meridian and Denali will have improved resistance
14	legs or the legs alone tilting but not the petals.	14	to tilt and anything that tilt might cause?
15	Q And what accommodation are you speaking	15	MR. O'CONNOR: Form and foundation.
16	of? Meaning that the tilt doesn't have	16	Excuse me. Object to the form of the question.
17	consequences beyond tilting or that what do you	17	THE WITNESS: Well, I haven't done any
18	mean by that?	18	analysis, but I recall the tests that Bard carried
19	A Yeah, I mean that the that the	19	out that showed that the Meridian was tilting just
20	·	20	as much as the I believe it was the Eclipse
	tilting I mean that the tilting would be	21	
21	self-limiting and the the driving force would		filter in the bench test that they carried out.
22	not be as continuous as it would be in the G2 and	22	BY MS. DALY:
23	Recovery filters, and, therefore, the extent of net	23	Q But what were the strains on the legs in
24	tilting of the filter is likely to be less in the	24	tilt?

54 (Pages 210 - 213)

A I didn't do that calculation.

25

case of the Simon than in the Recovery and the G2.

25

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	Page 214		Page 216
1	Q Okay. And it would be the strains that	1	Recovery or G2 filter?
2	would drive fracture perhaps?	2	A I may have seen those, but I don't recall the results.
3	MR. O'CONNOR: Object to the form of the		
4	question.	4	Q How far would a G2 or Recovery filter have
5	THE WITNESS: It would be the strains that	5	to tilt to be less effective at clot trapping than
6	would drive fatigue fracture, yes.	6	a Simon nitinol?
7	BY MS. DALY:	7	A I I don't know.
8	Q Okay. On page 14, we're still in C but	8	MR. O'CONNOR: Object to the form.
9	we're in the next paragraph of little C.	9	BY MS. DALY:
10	A Okay.	10	Q Then there's a next sentence that you
11	Q And it's talking about clot trapping by	11	just stopped at that semicolon and it says "The
12	the Simon nitinol.	12	tilting of the clot trap will not greatly increase
13	A Yes.	13	any likelihood of perforation of the caudal wall."
14	Q And tell me what your opinion is about the	14	Could you explain that to me?
15	Simon nitinol's ability to clot trap and tilt	15	A Well, I mean that the because the
16	versus Recovery or G2?	16	contact between the petals and the wall of the vena
17	A You mean to act as a clot trap?	17	cava is spread out over a significant length of the
18	Q Yeah. I thought what you were saying here	18	perimeter of the petals in the clot trap, that
19	was you were comparing a tilted Simon nitinol and		the that there would not be a tendency for the
20	its effectiveness to still capture clot versus	20	shape of the petals to try to aggressively
21	Recovery and G2 in tilt. Did I misinterpret	21	penetrate the wall of the vena cava.
22	that?	22	And, in addition, because the forces that
23	A No, in that paragraph I'm not doing that.	23	are being applied by the petals to the wall would
24	Q Okay. Did you do that analysis?	24	go down when the clot trap tilts, it's my that
25	A I need to look through this to see.	25	would contribute to the tendency for the likelihood
	Page 215		Page 217
١.	· · · · · · · · · · · · · · · · · · ·		
[	So as I write in the report at the bottom	1	of perforation to not increase.
2	So as I write in the report at the bottom of page 14	1 2	of perforation to not increase.  Q Okay. But the endothelialization of the
	of page 14		Q Okay. But the endothelialization of the
2 3	of page 14 Q Okay.	2	Q Okay. But the endothelialization of the petal-shaped dome into the vena cava in the Simon
2 3 4	of page 14 Q Okay. A you see there's a sentence that says	2	Q Okay. But the endothelialization of the petal-shaped dome into the vena cava in the Simon nitinol creates a stiff element? Am I describing
2 3 4 5	of page 14 Q Okay. A you see there's a sentence that says Q Yeah.	2 3 4 5	Q Okay. But the endothelialization of the petal-shaped dome into the vena cava in the Simon
2 3 4 5 6	of page 14 Q Okay. A you see there's a sentence that says Q Yeah. A "In the design of the SNF as depicted	2 3 4 5 6	Q Okay. But the endothelialization of the petal-shaped dome into the vena cava in the Simon nitinol creates a stiff element? Am I describing that right? I mean, it's it's got a lot of radial force and stiffness
2 3 4 5 6 7	of page 14 Q Okay. A you see there's a sentence that says Q Yeah. A "In the design of the SNF as depicted in Figure 2, the clot trap appears to remain	2 3 4 5 6 7	Q Okay. But the endothelialization of the petal-shaped dome into the vena cava in the Simon nitinol creates a stiff element? Am I describing that right? I mean, it's it's got a lot of
2 3 4 5 6 7 8	of page 14 Q Okay. A you see there's a sentence that says Q Yeah. A "In the design of the SNF as depicted in Figure 2, the clot trap appears to remain effective even after it tilts."	2 3 4 5 6 7 8	Q Okay. But the endothelialization of the petal-shaped dome into the vena cava in the Simon nitinol creates a stiff element? Am I describing that right? I mean, it's it's got a lot of radial force and stiffness MR. O'CONNOR: Object to BY MS. DALY:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Of page 14 Q Okay. A you see there's a sentence that says Q Yeah. A "In the design of the SNF as depicted in Figure 2, the clot trap appears to remain effective even after it tilts." Q Uh-huh. A "The tilting of the clot trap will not greatly increase any likelihood" that's not relevant to what you're asking. Q Okay. A So just because of the number and nature of the shape of the petals in the clot trap, it is my assessment that even after it's til tilted, it can remain effective as a device for trapping clots. Q Did you see any test of the Simon nitinol in tilt and see what the results were with a clot trapping test? A No, I haven't seen any results of such	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Okay. But the endothelialization of the petal-shaped dome into the vena cava in the Simon nitinol creates a stiff element? Am I describing that right? I mean, it's it's got a lot of radial force and stiffness MR. O'CONNOR: Object to BY MS. DALY: Q because of the way that the petal contacts the vena cava wall; is that correct? MR. O'CONNOR: Object to the form of the question. THE WITNESS: No, that that's not the reason it has a high degree of stiffness, it's simply the shape of the clot trap BY MS. DALY: Q Okay. A and how it's composed of wires that would give it its high stiffness. Q And then does it also endothelialize, this is the petal dome, does it endothelialize into the circumference of the vena cava?

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                                                                                                          Page 220
      make retrievability -- would that be something that
                                                                perforate the wall of the vena cava.
                                                          1
                                                                  Q Because there's no difference, in your
 2
      would also contribute to non-retrievability of the
                                                          2
 3
                                                          3
                                                                opinion, perforation in an SNF is going to drive
      Simon nitinol?
 4
            MR. O'CONNOR: Form and foundation.
                                                           4
                                                                strains, perforation in a G2 or Recovery is going
 5
            THE WITNESS: Yes, that would tend to
                                                          5
                                                                to drive strains, they could lead to fatigue?
      inhibit retrievability, which is what I said
                                                                  A That's true, although I really -- I would
 6
                                                          6
      earlier in answer to one of your questions.
                                                          7
                                                                like to make -- I should make that assessment
 7
      BY MS. DALY:
 8
                                                          8
                                                                numerically, because the geometry and the shape of
 9
        Q Okay. Then you talk about, in section D,
                                                          9
                                                               the legs, for example, make it -- play a role in
                                                                the exact results that you'd get out of such a
10
      I summarize that as you're saying the SNF is more
                                                         10
                                                                calculation. But in -- but broadly speaking,
      fracture-resistant than the R -- the Recovery or
                                                         11
11
12
      the G2. Is that what you're saying?
                                                         12
                                                               perforation would have the same effect on both
                                                         13
13
        A That's what I'm saying, yes.
                                                               models of filters.
14
         Q All right. And what features of the Simon
                                                         14
                                                                  Q And you did not do any specific comparison
      nitinol make it more fracture resistant?
                                                               of Simon nitinol design for resistance to any one
15
                                                         15
                                                               of the complications versus the G2X with some
16
        A I need to read this first, please.
                                                         16
17
        Q Sure.
                                                         17
                                                               change to its chamfer, you didn't do that specific
18
        A So the contribution that I'm addressing is
                                                         18
                                                               comparison?
19
      that it is usually perforation that increases the
                                                         19
                                                                  A No.
20
      strains up to levels that become dangerous in the
                                                         20
                                                                  Q You did not do that specific comparison
21
      fatigue behavior of the material, and since it's
                                                         21
                                                               with the electropolishing change to the Eclipse?
22
      unlikely, in my assessment from the engineering,
                                                         22
23
      that the SNF petals are not likely to perforate the
                                                         23
                                                                  Q Nor did you do it with the changes that
      wall, therefore it's unlikely that the strains
                                                         24
                                                               were brought forward from the Eclipse into the
24
                                                         25
                                                               Meridian and its addition to anchors, you didn't do
25
      driven by expansion and contraction of the vena
                                                                                                          Page 221
 1
      cava would be driven up to levels that would lead
                                                          1
                                                               that?
                                                          2
 2
     to fatigue failure in -- in relatively short
                                                                  A No.
3
     periods of time.
                                                          3
                                                                     MR. O'CONNOR: Form.
 4
        Q And did you do any modeling to show that?
                                                          4
                                                               BY MS. DALY:
 5
           MR. O'CONNOR: Object to the form of the
                                                          5
                                                                  Q Nor did you do it with the Denali
                                                               laser cut from a nitinol tube that also has
 6
     question.
                                                          6
                                                          7
7
                                                               anchors?
     BY MS. DALY:
                                                                     MR. O'CONNOR: Form.
8
        Q Using ---
                                                          8
                                                          9
                                                                     THE WITNESS: I didn't do any of those
9
        A I didn't.
10
        Q -- specifically the Simon nitinol and
                                                         10
                                                               analyses because it's my assessment that those
                                                         11
                                                               changes did not make a significant difference
11
     comparing it over.
                                                               to the -- to the filters in terms of reducing
        A I didn't do any modeling directly,
                                                         12
12
13
     although the analysis that I did would enable that
                                                         13
                                                               the danger that they present because of their
14
     kind of assessment.
                                                         14
                                                               failures.
                                                         15
                                                               BY MS. DALY:
15
        Q But you have not done that?
        A I haven't done it.
                                                         16
                                                                  Q Are you giving the opinion that the Simon
16
                                                               nitinol is an alternative safer product than the
                                                         17
17
        Q Okay. And what about the legs of the
18
     Simon nitinol, you just talked about your opinion
                                                         18
                                                               Bard retrievable products?
     that perforation is a driver of fracture and we've
                                                         19
                                                                     MR. O'CONNOR: Form.
19
20
     just talked about SNF legs being prone to
                                                         20
                                                                     THE WITNESS: I'm offering the opinion
                                                         21
                                                               that in the setting of permanent use of a filter,
21
     perforate, so what about them and fracture?
22
                                                         22
                                                               which the Recovery and the G2 and its successors
        A Well, the -- the perforation process would
23
     drive up the fatigue strains, and, therefore, it
                                                         23
                                                               can -- can be used as, that the Simon nitinol is a
     would make fatigue fracture more likely in the SNH 24
24
                                                               safer alternative.
                                                         25
                                                               BY MS. DALY:
25
     compared to the situation where its legs do not
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	in Re: Baru IVC Fin	<del></del>	Todavis Encounty
	Page 222	1	Page 224
1	Q But you would agree that the Simon nitinol	1	Bard filters.
2	will not serve populations of people whose doctors	2	Q And what analyses have you done that we
3	believe they need a retrievable filter, true?	3	have not talked about yet today that you claim is a
4	MR. O'CONNOR: Form.	4	model that would support some interrelatededness of
5	THE WITNESS: I'm I'm not offering that	5	any types of complications?
6	opinion. Was that could you ask the question	6	A Can you point me to where I write that in
7	again?	7	the reports?
8	MS. DALY: Can you read that question.	8	Q No, because I'm - I'm trying to just do
9	(Record read Lines 1-3.)	9	this kind of generally. I guess let me ask it a
10	MR. O'CONNOR: Form.	10	different way.
11	THE WITNESS: Well, since I'm not a	11	You talked you talked briefly about
12	medical doctor and I can't really answer that	12	perforation leading to fracture.
13	question properly, but since it's since it's	13	A Correct.
14	represented as a permanent filter, that would	14	Q Okay. So let's start with that one. Have
15	suggest that it's not meant to be used in	15	you done a model that actually shows that
16	situations where retrievability is is advised by	16	perforation creates a load that leads to a
17	the doctor.	17	fracture?
18	BY MS. DALY:	18	A Yes.
19	Q The Simon nitinol isn't?	19	MR. O'CONNOR: Form.
20	A The Simon nitinol.	20	THE WITNESS: Yes, I have.
21	Q Okay. Did you make any effort to look at	21	BY MS. DALY:
22	modifications that would have had to be made to the	22	Q And which of your analyses is that? Just
23	Simon nitinol filter to allow it to maintain what	23	describe which one.
24	you conclude is low complications rate but make it	24	A Well, the beam bending analysis where I
25	percutaneously retrievable?	25	consider both the G2 and the Recovery filters, the
	Page 223		Page 225
I	A No	1	arms of those filters, and I look at shapes which
2	MR. O'CONNOR: Form.	2	are consistent with different degrees of
3	THE WITNESS: I didn't look at that.	3	perforation through the wall of the vena cava and
4	MR. O'CONNOR: Okay. When you get to a	4	then I calculate the strains imposed on the filter
5	place where we can take a quick break?	5	by expansion and contraction of the wall of the
6	M\$, DALY: Yeah. Almost.	6	vena cava, and then I consider that in the light of
7	MR. O'CONNOR: Okay.	7	fatigue performance of the material.
8	MS. DALY: This is a good break point.	8	Q And so that's what I wanted to ask you for
9	MR. O'CONNOR: Oh, great.	9	each of these connections. So your alleged
10	MS. DALY: Can you tell us what our time	10	connection between perforation and tilt, have you
11	is.	11	done a model of that? And which one of it is?
12	THE VIDEOGRAPHER: This is the end of	12	Just point me to which one it is.
13	Media No. 3. We are going off record at 1454.	13	A So are you asking me have I looked at
14	(Recess taken.)	14	perforation that occurs first and then leads to
15	THE VIDEOGRAPHER: This is the beginning	15	tilt? Is that the
16	of Media No. 4. We are back on the record at 1508.	16	Q Yes.
17	BY MS, DALY:	17	A Is that how I interpret the question?
18	Q Dr. McMeeking, have you performed any	18	Q Or either or either way around.
19	actual tests on Bard retrievable filters to	19	A Well, I I've carried out assessments in
20	determine if an interrelatedness of complications	20	which the process of of perforation
21	actually exists?	21	I've done calculations where the process of
22	A Do you mean a bench test or	22	perforation leads to tilt of the filter, so I've
23	O Yes.	23	done finite element calculations in which that
24	A an experiment of some kind?	24	occurs as that tilting occurs as a consequence
25	I have not carried out any experiments on	25	of perforation. And it's in my report.
			and harmonia and an and an and an and an

	III Ne. Baid IVC Fit		
	Page 226		Page 228
1	And then in terms of the question of tilt	1	neighboring limbs that perforate or any combination
2	leading to perforation, I've considered the	2	of limbs that that perforate, because it's the
3	elevation of the loads that is associated with the	3	interaction between one limb and the one that's
4	tilt in terms of one leg having a higher or one	4	opposite on the clock that determines the degree of
5	arm having a higher load applied to the vena cava	5	strain that will develop as a consequence of the
6	than another, and concluded that that would lead to	6	motion of the vena cava wall.
7	more rapid perforation of one leg into the wall of	7	Q And the one that's on the opposite side of
8	the vena cava.	8	the clock, if it's perforating the same amount,
9	And, in addition, that's supported by	9	what then?
10	calculations that Dr. Briant has done in regard to	10	A Well, if if the two are perforating
11	comparing a tilted and untilted filter in terms of	11	on if they're opposite each other on the clock,
12	the forces that the limbs apply to the wall of the	12	then that is going to give you bigger strains than
13	vena cava.	13	if one alone on that pair of limbs perforates.
14	Q And then with respect to any of your	14	Q But you haven't done any specific modeling
15	opinions about interrelatedness of one complication	15	to look at the clock and try different sequences of
16	to the next, you agree that the relationships may	16	perforating limbs and see what the strains are?
17	well be patient-specific?	17	MR. O'CONNOR: Object to the form of the
18	MR. O'CONNOR: Object to the form of the	18	question.
19	question.	19	THE WITNESS: Other than what I just
20	THE WITNESS: I would I would assess	20	described, I haven't done that kind of modeling.
21	that in each in each patient, given the	21	BY MS. DALY:
22	differences in physiology, that different	22	Q Okay.
23	interactions can occur in terms of what the	23	A But I should say I don't think that that
24	implications or what the consequences of tilt and	24	kind of modeling is necessary to make the
25	perforation is on in that particular patient.	25	conclusions I just gave you.
	Page 227		Page 229
1	BY MS. DALY:	1	Q And have you determined an amount of
2	Q And that, for example, perforations	2	perforation that's required to start to increase
3	occurring at different places in the filter	3	the strain?
4	MR. O'CONNOR: Object to the form form	4	MR. O'CONNOR: Object to the form.
5	of the question.	5	THE WITNESS: Even a small amount of
6	MS. DALY: I'm not sure why you're	6	perforation will increase the strain.
7	objecting to that.	7	BY MS. DALY:
8	Q That perforations in different struts in a	8	Q Increase the strain to the point of
9	given filter may result in no increased strains	9	contributing to a fatigue fracture?
10	that will lead to a fracture; is that fair to say?	10	A I haven't well, I have in the in the
11	MR. O'CONNOR: Object to the form of the	11	calculations that are I draw your attention to
12	question.	12	my report where in one section there are a whole
13	THE WITNESS: No, I think in every case,	13	lot of tables and the
14	that perforation of one limb will lead to an	14	Q We're looking
15	increase in strains in the filter compared to what	15	A tables
16	you get in an unper did I say perforation?	16	Q at Exhibit 2?
17	BY MS. DALY:	17	A Yes. Exhibit 2.
18	Q Uh-huh.	18	Q Okay.
19	A We're talking about perforation.	19	A And we're looking at Section well, I
20	So that perforation of one limb would	20	can do it in terms of page numbers.
21	increase the strains in that limb and the limb	21	Q Yeah.
22	opposite it compared to what you would get in an	22	A We're looking at pages 45 or maybe 44
23	unperforated filter, and this would occur whether	23	through
24	it's two neighboring filters sorry, two	24	Q Okay.
25	neighboring limbs that perforate or three	25	A through page 53 or so. Yeah, 53. And

	III Re: Bard IVC FIII	, OI 5 I	
	Page 230		Page 232
1	in each of these tables there's a calculation for	1	Can you read what I started to say.
2	different degrees of perforation that has taken	2	(Record read as follows:
3	place for a pair of arms which are on the opposite	3	"Have you done any work to
4	side of each other on the clock.	4	look at the probabilities of,
5	Q Right.	5	for example, fracture in")
6	A And the resulting strain is in the table,	6	BY MS. DALY:
7	and one can compare the strain in the table with	7	Q Fracture in a filter that has nothing
8	the fatigue limit of the material and when the	8	going on but two perforating arms on opposite sides
9	strain in the table crosses the fatigue limit, then	9	of the clock to, what was it, 3.5 millimeters out?
10	that will begin to induce failures which will	10	MR. O'CONNOR: Object to the form of the
11	eventually happen if the number of cycles of	11	question.
12	loading occurs to take the material to its to	12	THE WITNESS: I'm sorry, could you repeat
13	its fracture condition as a consequence of the	13	the question.
14	cyclic loading of the material.	14	BY MS. DALY:
15	Q So this section that's here at 45 that	15	Q Yeah.
16	you've just described is where you compare the	16	Have you done any work to look
17	the arms perforating on opposite sides of the	17	statistically at probabilities of fil of when
18	clock, if you will?	18	filters will fracture based on perforations that
19	A That's correct, yes.	19	they have present, tilt they have present, any of
20	Q Okay. All right.	20	the complications?
21	A Yes.	21	MR. O'CONNOR: Form.
22	Q And what is the least perforation that you	22	THE WITNESS: I haven't done statistical
23	considered, the least amount of perforation?	23	assessments of that situation.
24	A Well, I'd have to compare every result and	24	BY MS. DALY:
25	every table, which could take some time. I	25	Q Okay. And similarly, you have not done
	Page 231		Page 233
1	well, the least	1	any statistical assessment of the probability of a
2	Q I mean, do you know the range? That's	2	filter that is has experienced one complication,
3	what I'm saying. Do you	3	let's say perforation, having another complication,
4	A Well, actually the least perforation I	4	let's say tilt?
5	considered was zero.	5	MR. O'CONNOR: Objection.
6	Q Okay.	6	THE WITNESS: Can I
7	A And then	7	MR. O'CONNOR: Form.
8	Q Show me what page is your highest shown.	8	THE WITNESS: I'd like to augment my
9	A Well, in some of the tables I don't	9	previous question (sic), which is that if I assume
10	actually give the results, so of all the four	10	in certain sizes of the vena cava if the
11	tables I can't give you an answer, but in the	11	perforation continues to the extent that I've
12	tables where I do give the results, the answer is	12	assumed, that the probability of the frac the
13	in Table 2 at the bottom, on the bottom line where	13	fatigue the limb failing by fatigue after a
14	the degree of perforation is 3.5 millimeters.	14	certain number of cycles is very high, and if
15	Q Okay. And that's page what?	15	and if you take a large number at a certain stage,
16	A Page 49.	16	over half of those filters would fail.
17	Q 49. That's where I am. Okay.	17	BY MS. DALY:
18	MR. O'CONNOR: How do you take it? Black?	18	Q In a certain amount of time, what does
19	THE WITNESS: Yes, black, please. Thank	19	that mean?
20	you.	20	MR. O'CONNOR: Object to the form.
21	BY MS. DALY:	21	THE WITNESS: Can you can you tell me
22	Q Have you done any work to look at the	22	what I said.
23	probabilities of, for example, fracture in	23	MS. DALY: Yeah, would you re-read his
24	(Brief interruption.)	24	last answer, because he had something about a
25	MS. DALY: I forgot what I was saying.	25	certain amount of time.

	In Re: Bard IVC Filt	.0191	Toddols Diability
	Page 234		Page 236
1	(Record read as follows:	1	MR. O'CONNOR: Form.
2	"I'd like to augment my previous	2	THE WITNESS: But I said I can compute it.
3	question (sic), which is that	3	BY MS. DALY:
4	if I assume in certain sizes of	4	Q The number of cycles? What number of
5	the vena cava if the perforation	5	cycles then?
6	continues to the extent that I've	6	A Well, for example, in if the number is
7	assumed, that the probability of	7	in a is exactly equal to the fatigue limit of
8	the limb failing by fatigue after	8	the material, then the number of cycles involved
9	a certain number of cycles is very	9	would be 10 to the 8.
10	high, and if you take a large	10	Q So have you done that type of calculation
11	number at a certain stage, over	11	for any individual person?
12	half of those filters would fail.")	12	A No, I have not.
13	BY MS. DALY:	13	Q Okay. So you don't have from a real-life
14	Q At a certain number of cycles. What are	14	person any example of where you followed them
15	those what's the certain number of cycles?	15	through imaging, saw what was happening with
16	A Well, it depends on the strain which is	16	perforation or tilt or movement of the filter, put
17	involved, and the bigger the strain, the smaller	17	these calculations on it and said "A-ha, they had a
18	the number of cycles.	18	fracture"?
19	Q So you're saying in a given filter, if	19	MR. O'CONNOR: Object to the form of the
20	that given filter has the condition that you've	20	question.
21	modeled, after a certain number of cycles, that you	21	THE WITNESS: I have not gone through such
22	haven't computed what those are, it's more it's	22	a process.
23	50 percent likely to to fracture?	23	BY MS. DALY:
24	A That's correct.	24	Q Okay.
25	Q But we don't know what the cycle numbers	25	MR. O'CONNOR: How do you spell "a-ha"?
	Page 235		Page 237
1	are?	1	MS. DALY: She knows how to spell it.
2	A Well, if we look at the Bard data and we	2	Q All right. We are going to case-specific.
3	take that as the true reflection of how the	3	Starting with Ms. Booker's case. And
4	material behaves, then that can be used to look at	4	starting with your report in Ms. Booker's case.
5	the number of cycles that will give you that	5	A Okay.
6	50 percent level of the of the limbs failing.	6	Q All right. You say in your Booker report,
7	Q So in everybody who's got a perforation to	7	page 2, paragraph 1 that, quote, "I have determined
8	the extent of what? What number? What	8	to a reasonable degree of engineering and
9	A 3.5 millimeters. This number is what	9	scientific certainty that Ms. Booker's G2 filter
10	would occur if the filter is perforated to the	10	experienced all of the failure modes consistent
11	extent that it goes back to its designed shape.	11	with defects inherent in that filter."
12	Q So in everybody that has a perforated	12	Is that what you say?
13	filter 3.5 millimeters or more outside the vena	13	A That's what I said.
14	cava in some number of cycles that you can't	14	Q Okay. Then in that same report on page 1,
15	compute	15	and it's bullet No. 2, you state that "The filter
16	A Well, we have to be careful how we	16	caudally migrated 3 centimeters, tilted 18 to 20
17	interpret this number, because the 3.5 millimeters	17	degrees with the tip to the wall, 8 of 12 struts
18	is where the elbow is outside of the vena cava, so	18	perforated, many to adjacent organs, vessels or
19	there's also the the lower arm would be outside	19	structures, and three struts fractured." Right?
20	the vena cava as well, so this is a very large	20	A That's correct.
21	element of the limb outside of the vena cava.	21	Q What did you do to determine that
22	Q Okay. So very large element is outside	22	Ms. Booker's filter experienced those things?
23	the vena cava and in a certain number of cycles	23	A I read the reports of Dr. Hurst and
24	that you cannot compute, 50 percent of those will	23 24	Dr. Muehrcke, and I also looked through medical
24 25	fail?	2 <del>4</del> 25	records myself, although I primarily relied on
43	tait:	رے	records mysen, annough I primarily rened on

July 6, 2017

	In Re: Bard IVC Filt	ers i	roducis Liability
	Page 238	Γ	Page 240
1	Dr. Hurst and Dr. Muchrcke, although my reading of	1	Q Let me see your oh, right here. The
2	the medical records is consistent with what I saw	2	first word there. "Multiple legs penetrating"
3	in the reports by Dr. Hurst and Dr. Muehrcke.	3	A Okay. Start from there?
4	Q So based on the medical records that you	4	Q Yes.
5	read, you can say that somebody other than Hurst	5	A All right.
6	and Muehrcke has said the filter caudally migrated	6	Q "Multiple legs penetrating through the IVC
7	3 centimeters	7	wall, with one extending into the aorta 8
8	A Oh, sorry, I should so what I was able	8	millimeters." All right. That's the kind of
9	to determine is that some of these failure modes	9	information that you had to accept as accurate from
10	Q Okay.	10	Dr. Muehrcke?
11	A occurred.	11	A That's correct.
12	Q But not with tiny detail?	12	Q All right. How about the fact of tilt or
13	A Not not with this detail.	13	caudal migration, is that something you were able
14	Q Okay.	14	to determine yourself?
15	A And not all of them from the medical	15	A I did not determine that myself, and I
1	records. The others were gathered from the medical	16	don't recall whether I saw reference to tilt in the
16		17	medical records.
17	expert reports.	18	Q All right. And then he goes on and says
18	Q And you've said many times today you're not a doctor, You don't deem yourself to be	ı	"Additionally, filter struts perforated the small
19	· · · · · · · · · · · · · · · · · · ·	19 20	bowel, psoas muscle, lumber vein at L4." Again,
20	qualified to read medical records and interpret	ı	that's not something that you determined on your
21	whether what the doctor reported is accurate?	21	own?
22	MR. O'CONNOR: Form.	22	
23	THE WITNESS: That's correct.	23	A No, not by myself.
24	BY MS. DALY:	24	Q All right. And then Hurst's report, page
25	Q And you do not deem yourself to be	25	5 and 6, let's look at him.
	Page 239	١.	Page 241
1	qualified to read imaging to a level that would	1	A Oh, Hurst. Sorry.
2	allow you to determine the depth of a perforation	2	Q He put page numbers on there, which is
3	or the amount of tilt, that kind of thing?	3	good. And he starts with, like paragraph little C,
4	A I didn't read imaging in the in four of	4	he's talking about the the filter having no tilt
5	these cases, so and I don't I don't claim to	5	and its placement no tilt, no fracture, and its
6	be an expert in reading such imaging.	6	placement at the right pedicle of the L2?
7	Q Okay. Muchrcke's report, if you want to	7	A Yes.
8	look at that, at page 8, the top paragraph, and I	8	Q All right. This is not imaging you looked
9	hope I gave you ones that have page numbers on it		at yourself and made your own conclusions?
10	because he didn't number his. Do yours have page	10	A No, I did not look at the imaging.
11	numbers?	11	Q All right. And then he goes on in E and G
12	A No.	12	on the next page and he gives very specific
13	Q Shoot.	13	interpretations of the imaging, degrees of tilt,
14	A So when I get to 8, it's the second to	14	which arms at which position are in a Grade III or
15	last page, is that	15	Grade II. You see those kinds of things?
16	Q Yeah. Sorry. At the top he says "There	16	A Yes, I see that, yes.
17	are multiple legs penetrating through the IVC	17	Q All right. And again, you would rely on
18	wall," and then he describes "a leg extending into	18	Dr. Hurst for that?
10	the aorta 8 millimeter"	19	A That
19		20	Q For that kind of detail?
l .	A Could you tell me which paragraph we're	20	Z 10. mat min 01 aniam.
19 20	A Could you tell me which paragraph we're on.	21	-
19 20 21	on.		A Yes, that kind of detail, yes.
19 20 21 22	on.  Q Yeah, I'm at the very top here.	21 22	A Yes, that kind of detail, yes.  Q Okay. Do you know what he means by a
19 20 21	on.	21	A Yes, that kind of detail, yes.

61 (Pages 238 - 241)

1 A I'd have to look back at papers to find 2 the definition of Grade III, but I have come across 3 it in papers but I can't quote it to you. 4 Q Have you ever talked to him about what his 5 definition is of Grade II 6 A No, I have not. 7 Q - or Grade III? 8 A No. 9 Q Okay. All right. Whoops. 10 And it appears that Dr. Muehrcke did not 11 read imaging as in as much detail as Dr. Hurst; 12 would you agree with that? 13 A I don't have any opinion on that. 14 MR. O'CONNOR: Form. 15 BY MS. DALY: 16 Q Okay. You don't know if they're 17 consistent in what they've read or they're 18 inconsistent? 19 A I don't know. 20 Q Okay. Dr. Hurst and Dr. Muehrcke both say in their reports, and you could look at Dr. Hurst's opinions in at paragraph 4, which is on page 8, and go to page I'm sorry - I'm sorry, go to page 12. Under his opinions, page 12, H. Hurst 25 says "In rendering my opinions in this matter, I  Page 243 1 took into consideration Ms. Booker's comorbidities, medical history, and so on?  1 A No, I don't. 1 MR. O'CONNOR: Object to the form taking into consideration these com medical history, and so on?  4 A No, I don't.  5 MR. O'CONNOR: Object to the form taking into consideration these com medical history, and so on?  4 A No, I don't.  5 MR. O'CONNOR: Object to the form taking into consideration these com medical history, and so on?  6 BY MS. DALY:  7 Q Okay. Did you take into consideration for Ms. Booker's comorbidities, medical history, and so on?  8 A No, I don't.  9 Q Do you know if she had any medical history, and so on?  10 A No, I didn't.  11 Q Do you know if she had any medical history, comorbidities, medical history and prexisting conditions?  12 history, comorbidities, preexisting conditions?  13 A I I'm not aware of any. I I jus don't know. I haven't gotten the informat of the retrieving doctor in Ms. Booker's case, we migration?  15 Q Did he verify whether there was on migration?  16 A No, I didn't.  17 Q Did you read the deposition of the retrieving doctor in Ms. Booker's comorbiditie	rm. tion any istory or al ons that or filter in
the definition of Grade III, but I have come across it in papers but I can't quote it to you.  Q Have you ever talked to him about what his definition is of Grade II  A No, I have not.  Q — or Grade III?  A No.  Q Okay. All right. Whoops.  And it appears that Dr. Muehrcke did not read imaging as in as much detail as Dr. Hurst; would you agree with that?  A I don't have any opinion on that.  MR. O'CONNOR: Object to the form of Ms. Booker's comorbidities, medical history, and so on?  A No, I don't.  BY MS. DALY:  Q Okay. Did you take into consider of Ms. Booker's comorbidities, medical history, and so on?  A No, I don't.  MR. O'CONNOR: Object to the form of Ms. Booker's comorbidities, medical history, and so on?  A No, I don't.  MR. O'CONNOR: Object to the form of Ms. Booker's comorbidities, medical history, and so on?  A No, I don't.  MR. O'CONNOR: Object to the form of Ms. Booker's comorbidities, medical history, and so on?  A No, I didn't.  Q Do you know if she had any medical history, and so on?  A No, I didn't.  Q Do you know if she had any medical history, and so on?  A No, I didn't.  A I I — I'm not aware of any. I — I just don't know. I haven't gotten the informated of the performance of have in their reports, and you could look at Dr. Hurst's opinions in — at paragraph 4, which is on page 8, and go to page — I'm sorry — I'm sorry, go to page 12. Under his opinions, page 12, H. Hurst says "In rendering my opinions in this matter, I  Page 243  1 took into consideration Ms. Booker's comorbidities, medical history and preexisting problems."  A No, I didn't.  Q Did you know if she had any medical history, and so on?  A No, I didn't.  Q Did you read the deposition of the retrieving doctor in Ms. Booker's case, we migration?  A No, I did not.  Q Did he verify whether there was comigration?  A No, I did not.  Q Did he verify whether there was comigration?  A No, I did not.  Q Did he verify whether there was comigration?  A No, I did not.  Q Did he verify whether there was comigration?  A I don't know. Unle	rm. tion any istory or al ons that or filter in
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4 A I see that he says that. 4 know.	h I'd
1	ouldn't
5 Q And then Muehrcke on the last page of his 5 Q Okay. Whatever Dr. Kang had to	
	ay you
6 report in Booker, just before his signature page, 6 did not rely on in giving this Booker repo	t; is
7 paragraph second from the bottom, he says exactly 7 that fair?	
8 the same thing. "I was" "I am aware of 8 A No, I did not.	
9 Ms. Booker's comorbidities, medical history and 9 Q Okay. Did you read any of the Ba	
10 preexisting problems, and these are taken into 10 case-specific medical experts' reports in t	e
11 consideration in rendering my opinions." 11 Booker case?	
12 Do you see he says that? 12 A No.	
13 A The meaning of the sentence is the same, 13 Q You conclude that the events that c	
14 yes. 14 to Ms. Booker's filter are consistent with	
15 Q Okay. What comorbidities, medical history 15 kinds of failures that you've discussed in	
16 or conditions did they take into consideration as 16 reports and we've discussed today, right?	our
17 far as you know? 17 A That's correct.	our
18 MR. O'CONNOR: Form. 18 Q And, therefore, with respect to any	
19 THE WITNESS: Well, I don't know except 19 or any perforation or fracture or migration	tilt
20 what's in this report, so I'd have to read it and 20 might occur in a Bard filter, you're of the	tilt that
21 then identify what other problems the patient had, 21 that they were caused by filter defects?	tilt that
22 but I I'm 22 A That's my opinion in that the the	tilt that opinion
23 BY MS. DALY: 23 design and the testing of them was insuffi	tilt that opinion
24 Q And that really wasn't a good question. 24 reveal whether they were adequate to the	tilt that opinion r cient to
25 I'm sorry. 25 they were expected to perform in the patie	tilt that opinion r cient to ask that

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1	D . 046	$\Gamma$	D 016
1	Page 246 Q Okay.	1	Page 248 BY MS. DALY:
2	A And, therefore, that in in that sense,	2	Q And you know that Bard warns in its IFU
3	these filters are dangerous to the to the	3	that those are risks associated with these filters,
4	patient.	4	true?
5	Q And and by "dangerous," again, you're	5	MR. O'CONNOR: Form, Foundation.
6	not saying that from a medical standpoint, correct,	1 -	THE WITNESS: I know that they warn of
7	whether when something happens to the filter it	7	risks. I'm not completely familiar with with
8	hurts them?	8	what risks they warn of.
9	A That's correct, I'm simply observing	9	BY MS. DALY:
10	that that these events, especially the fracture	10	Q And going back to my question, you also
11	of a filter, seem like, or they are, undesirable	11	have not attempted to do any calculations specific
12	phenomena that I would not like to have happen	12	to Ms. Booker putting in as variables which of her
13	inside me.	13	filter struts were perforating or the extent to
14	Q You have not attempted to model or do any	14	which they were perforating, correct?
15	calculations with respect to Ms. Booker's vena cave		A Correct.
16	size?	16	Q You have also not done any calculations in
17	A No.	17	her case putting in this alleged caudal migration
18	Q Her respiratory rate?	18	and what the extent of that caudal migration was,
19	A No.	19	correct?
20	Q Her Valsalva experience?	20	A Correct, I have not put that into any
21	A No.	21	calculation.
22	Q Her the quality of her vena cava tissue	22	MR. O'CONNOR: Object to form.
23	or the quality, flexibility, inflexibility, of	23	BY MS. DALY:
24	nearby organs?	24	Q Nor have you put in any calculation on the
25	MR. O'CONNOR: Object to the form of the	25	degree of tilt that Dr. Hurst is reporting,
	Page 247		Page 249
1	question.	1	correct?
2	THE WITNESS: I haven't looked into that	2	A No, I have not done that.
3	in any manner, although I should say that in my	3	Q So you have not generated any modeling
4	assessment, these failures are entirely predictable	4	specific to Ms. Booker that you can tell us "Here
5			· ·
1	in the sense that they're going to occur in in	5	were the strains that were going on specifically in
6	some patients and they're going to be some they	5 6	· ·
6 7	some patients and they're going to be some they are going to be phenomena that will occur in some	6 7	were the strains that were going on specifically in Ms. Booker in these locations at these times during the time her filter was in situ"?
6 7 8	some patients and they're going to be some they are going to be phenomena that will occur in some cases.	6 7 8	were the strains that were going on specifically in Ms. Booker in these locations at these times during the time her filter was in situ"?  A No, I haven't.
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	III Re. Datu I Ve I III	C13 1	
	Page 250	1	Page 252
1	A Because the information that I had didn't	1	Q Paragraph 4, little 2.
2	allow me to tell whether it was actually a G2 or a	2	A Okay.
3	G2X filter that was involved.	3	Q Hurst says that the filter was implanted,
4	Q Okay. Then in your report page 1, bullet	4	that's little 1, was implanted on 2-25-11, and then
5	2, you note that Mrs. Hyde's filter tilted,	5	little 2I he says "Filter subsequently caudally
6	caudally migrated, perforated in multiple struts,	6	migrated, with penetration of multiple arms and
7	and an arm fractured and embolized to her heart,	7	legs, ultimately led to fracture of a stabilizing
8	right?	8	arm that went to the right ventricle."
9	A Correct.	9	Do you know whether in her case the
10	Q When you say "arm," do you mean arm or d	1	fracture was an arm or a leg?
11	you mean a strut?	11	A Well, reading this section, I assumed it's
12	A I mean a strut.	12	an arm because of how that paragraph was written.
13	Q So it could have been an arm or a leg?	13	Q Do you know for sure?
14	A Could have been an arm or a leg.	14	A I don't know for sure.
15	Q You don't know which?	15	Q Okay.
16	A Correct.	16	A Since often, as I think you probably know,
17	Q All right. Do you know what did you do	17	there are different terms used for different
18	to determine if Ms. Hyde experienced these events		struts.
19	or when?	19	Q Right. Some people call all the pieces
20	A I read the reports by Dr. Hurst and	20	struts, some call them arms.
21	Dr. Muehrcke.	21	A Right.
22	Q Okay	22	Q Okay. Now, in this report on Ms. Hyde,
23	A And I read her medical rec the medical	23	different from the report that Dr. Hurst did on
24	records I had available to me, and the combination	24	Booker, if you look through here with me there is
25	of those sources gave me the information, which is	25	not a detailed interpretation by him of imaging
	Page 251		Page 253
1	in these bullet points.	1	where he says, you know, the 1:00 arm is doing
2	Q Did you principally rely on what either	2	this, the 6:00 arm is doing that?
3	Dr. Muehrcke or Dr. Hurst said?	3	MR. O'CONNOR: Object to the form of the
4	A I principally relied on them.	4	question.
5	Q Okay. So let's look at Muehrcke first,	5	BY MS. DALY:
6	and his report on page 1, paragraph 1, lists as her	6	Q Correct?
7	failure modes there before the colon, "Caudal	7	A Well, sorry, can you draw me draw my
8	migration, tilt fracture, perforation, penetration	8	attention to
9	of adjacent organs and structures, and embolization		Q Yeah. I don't see where he said that
10	of a fracture of the filter that fractured."	10	anywhere.
11	Do you see that?	11	A Well, again, I'd have to look through the
12	A I see that, yes.	12	whole report to confirm that but
13	Q Then Dr. Hurst oh, and he doesn't I	13	Q Well, he doesn't.
14	note that Dr. Muehrcke doesn't cite to any medical	14	A Yeah.
15	records where he got that information. I mean, he	15	Q And you're welcome to look through that,
16	lists medical records he saw but I mean right where		but you'll see he doesn't with the specificity he
17	he's talking about those things, he doesn't cite to	17	did for Booker. He doesn't say which which
18	a to a medical record, correct?	18	filter strut is perforating to what degree on what
19	A Yeah, there's no citation right there.	19	image. That's my only point.
20	I'd have to review the whole report to see whether	20	MR. O'CONNOR: Object to the form of the
21	he cites specific records elsewhere.	21	question.
22	Q He he lists well, I thought he	22	THE WITNESS: That would appear to be the
23	listed records but I don't see them. At any rate,	23	case.
24	let's go to Hurst. Page 6.	24	BY MS. DALY:
25	A Okay.	25	Q Okay. So what we don't have from
25	**		

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l .	Page 254	1	Page 256
I	Dr. Hurst and you're welcome to look at	1	medical history and preexisting conditions. Same
2	Dr. Muehrcke's too, he doesn't do it either what	2	question I had for you for Ms. Booker and Ms. Hyde:
3	we don't have from Muehrcke or Hurst is any detail	3	You don't know what Dr what Dr. Hurst or
4	of information about which struts perforated, how	4	Dr. Muehrcke took into consideration about those
5	much they perforated or when they perforated	5	items?
6	relative to each other or relative to the fracture?	6	A No, I don't know how what they took
7	MR. O'CONNOR: Form.	7	into consideration.
8	BY MS. DALY:	8	Q Okay. And you did not take those things
9	Q Is that fair?	9	into consideration in your opinions?
10	MR. O'CONNOR: And foundation.	10	A No, I did not.
11	THE WITNESS: That would appear to be the	11	Q Okay. Do you know that it's Dr. Kuo that
12	case. BY MS, DALY:	12	removed Ms. Hyde's filter and strut?  A I don't recall whether I read that
14		14	
1	Q Okay. Now, with respect to Ms. Hyde, do	15	somewhere but I may well have, but
15	you have any information on your own or from  Dr. Hurst or Dr. Muehrcke about what her yena cava	16	Q Do you know whether he reported that there
16 17		17	was caudal migration or not?
18	tissue quality, firmness, flexibility was?  A I have no information on that.	18	A I read the medical records and that may
19	Q Or what her blood flow was?	19	have been in there, but I don't recall whether it was.
20	A No, no information on that.	20	Q Was there anything that he provided, as
21	Q What her respiration rate was?	21	far as you recall, about when any migration of her
22	A I have no information on that.	22	filter, if it happened, began and what its
23	Q What her experiences were with Valsalva?	23	progression was over time?
24	A No information on that.	24	A No, I don't recall that. It it may
25	Q Do you know how the sleep apnea that she's	25	have been in the medical records I read, but I
1	Page 255 been diagnosed with may have impacted her filter?	1	Page 257 don't recall the details.
2	A No, I haven't thought about that.	2	Q Did you take any details from Dr. Kuo's
3	Q Okay. What about her smoking history, how	ı	operative report or his deposition about what he
4	that might have impacted the filter?	4	
1	mat might have impacted the inter;		onserved with respect to pertoration of any of the
1.5	MR O'CONNOR: Form Foundation	l	observed with respect to perforation of any of the
5	MR. O'CONNOR: Form. Foundation. THE WITNESS: I'm not an expert in	5	struts of the filter when he went to retrieve it?
6	THE WITNESS: I'm not an expert in	5 6	struts of the filter when he went to retrieve it?  MR. O'CONNOR: Object to the form of the
6 7	THE WITNESS: I'm not an expert in medicine, so I'm not able to make that to	5 6 7	struts of the filter when he went to retrieve it?  MR. O'CONNOR: Object to the form of the question.
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July 6, 2017

	In Re: Bard IVC Filt		roddold Eldollity
	Page 258		Page 260
1	complex procedure performed by Dr. Kuo of the	1	A Well, it was implanted as a filter in her
2	filter fragment from the heart.	2	vena cava.
3	A Yes.	3	Q Okay.
4	Q Do you know what "complex procedure"	4	A And it I rely on Dr. Hurst and
5	means?	5	Dr. Muehrcke for that information.
6	A Well, again, since I'm not a medical	6	Q And did you know that in her case she'd
7	expert I don't know precisely what it meant, but	7	had recurrent DVT and pulmonary embolus in the
8	since the since the fragment was in the heart,	8	past?
9	it must have been a complicated procedure that was	9	A I may have read that in her medical
10	undertaken.	10	records but I don't recall.
11	Q I guess my did you borrow that term	11	Q And you're not when you say the filter
12	from some medical thing that you read as opposed to	12	was used as intended, you're not intending to make
13	your own opinion that it was complex?	13	any comment about whether she was a proper
14	MR. O'CONNOR: Form.	14	candidate for the filter medically?
l		15	A No. No.
15	THE WITNESS: It was my interpretation of what I read in the Hurst and Muehrcke reports and	16	MR. O'CONNOR: Form.
16			BY MS. DALY:
17	possibly also what I read in the medical records	17   18	Q Okay. You said that the filter was
18	from Dr. Kuo's reports.		
19	BY MS. DALY:	19	properly implanted. On what information do you
20	Q Did you read what Dr. Kuo's procedure	20	rely for that?
21	notes indicated that the procedure entailed, the	21	A Well, I rely on Dr. Hurst and Dr. Muehrcke
22	procedure that he did entailed?	22	who who, as I recall, state that the
23	A I believe I did read it, but I don't	23	implantation was successful.
24	recall any details.	24	Q Okay. You've made no independent
25	Q Do you recall that he described for the	25	assessment of that?
	Page 259		Page 261
1	strut retrieval that it was a single snare attempt	1	A No.
2	of the filter and immediate removal of the strut?	2	Q Okay. The next thing you said is that no
3	A I don't recall that.	3	athon course of the failures of that filter that
I 4			other causes of the failures of that filter that
4	MR. O'CONNOR: Form.	4	there were no other causes of the yeah, there
5	BY MS. DALY:		there were no other causes of the yeah, there were no other causes of the failures of that
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MS. DALY:  Q Okay. Would you defer to medical people to describe how complex or difficult this procedure was for Ms. Hyde?  A Well  MR. O'CONNOR: Form.  THE WITNESS: going with a catheter inside the heart and with a snare seems like a complex procedure to me, but I would defer to medical experts in terms of where that scales on the level of complexity.  BY MS. DALY:  Q Okay. In your report on page I, bullet 4, you state that in Ms. Hyde's case the filter was "used as intended, properly implanted and there were no other causes for failure," so I want to talk about those one at a time. Okay?  A Okay.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	there were no other causes of the yeah, there were no other causes of the failures of that filter. What does that mean, first of all?  A Well, the I it means that the experiences that I've described that implanted filters go through when they're implanted in the vena cava, such as expansion and contraction of wall of the vena cava and blood clots hitting it and the other things that we've talked about, were the causes of the failure of the filter.  Q But do you agree with me that you did not investigate anything specific about Ms. Hyde's anatomy?  A No, I didn't investigate that.  Q Or her medical conditions?  A No.  Q Medical history?  A I did not review other than the medical records that were related to the filter.

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١.	Page 262		Page 26
1	filter?	1	catching clots, for example, to calculate any
2	A Correct.	2	what strains were on her filter or any portion of
3	Q Okay. Now, do you understand that nobody	1	her filter at any time it was in situ, true?
4	has had the opportunity to examine either the	4	MR. O'CONNOR: Form.
5	retrieved filter or the retrieved piece of	5	THE WITNESS: True, I have done none of
6	Mrs. Hyde's filter?	6	that.
7	A I need to look	7	BY MS. DALY:
8	MR. O'CONNOR: Form.	8	Q Okay. All right. Let's talk about
9	THE WITNESS: at my report to see what	9	Ms. Jones. As with the previous two Bellwether
10	it what I obtained from the information.	10	reports, on page 1 actually, I'm sorry, it's at
11	Well, I don't comment on that, so I don't	11	page 2 at the top of the page you say again,
12	know where the filter is and where the fragment is.	1	"I've determined to a reasonable degree of
13	BY MS. DALY:	13	engineering and scientific certainty that
14	Q Okay. You have not seen any report from	14	Ms. Jones' Eclipse filter experienced all the
15	Dr. Richie, for example, or Dr. Fasching examining	1	failure modes consistent with defects inherent to
16	that filter?	16	that filter," correct?
17	A No.	17	A Yes, that's what is written, yes.
18	Q So what we don't have as a piece of this	18	Q And then on page 1, bullet 4 of your
19	puzzle is whatever that filter or fragment might	19	report, you list complications for Ms. Jones as
20	have shown us that would give us any information	20	filter tilt, migration, and one strut fractured,
21	about the fracture, correct?	21	correct?
22	MR, O'CONNOR: Form.	22	A Let me read through the information.
23	THE WITNESS: Well, I don't know whether		Yes, they're all there, yes.
24	Dr. Fasching or Dr. Richie have inspected the	24	Q And then you note that the in situ
25	filter, but if they haven't inspected the filter,	25	fragment is in her right pulmonary artery?
	Page 263		Page 265
1	then we don't have such information unless someone	I	A Yeah, at the time that I wrote this
2	else has inspected it for anyone in the in the	2	report, that was the information available to me.
3	case.	3	Q Do you know anything new now?
4	BY MS. DALY:	4	A I don't know anything else
5	Q All right. Okay. Then you concluded	5	Q Okay.
6	that in your report that the events that	6	A since then.
7	occurred with Ms. Hyde's filter were consistent	7	Q So once again, as you said with the last
8	with the kind of failures that you have discussed	8	ones, you principally relied on Dr. Hurst and
9	in your prior reports and in and in this	9	Dr. Muehrcke's report of what was happening with
10	deposition with me today, right?	10	this patient, correct?
11	A Correct.	11	A That's correct.
12	Q Okay.	12	Q All right. So Dr. Muehrcke on page 1 of
13	A So they're they're consistent and they	13	his report, it's about the fourth line down, he
14	support my assessment of those of those failure	14	says the Eclipse filter implanted in her had the
15	modes.	15	following failure modes, and he has caudal
16	Q Well, they're consistent with what you	16	migration, tilt and fracture of the filter, with
17	with the modes you've talked about, correct?	17	embolization to the pulmonary vascu
18	A Correct.	18	vasculature. Do you see that?
19	Q All right. But you have done no modeling	19	A I see that, yes.
20	or calculations specific to anything about	20	Q Okay. And again, he does not you can
21	Ms. Hyde, including you didn't calculate her vena	21	flip through he does not discuss in any detail
22	cava size, respiratory rate, Valsalva experience,	22	at all where he gets that information.
	any other medical condition she had, extent of her	23	MR. O'CONNOR: Object.
23	any other medical condition she had, extent of her		MIC O COMMON. Object.
23 24	perforations, distance of her caudal migration,	24	BY MS. DALY:
	·		

i	mile: Baid IV C I in	7	
	Page 266	Ι.	Page 268
1	6, which is four yeah, page 6 in.	1	tilt, the only thing I see is the 4 percent, which
2	MR. O'CONNOR: I object to the form of the		I'm not sure what that means, we normally you
3	question.	3	and I normally talk about that in degrees, right?
4	THE WITNESS: Sorry, is that a question?	4	A Correct. Yeah.
5	BY MS. DALY:	5	Q All right. So then let's look at
6	Q Yeah.	6	MR. O'CONNOR: Belated objection to the
7	A What's the question?	7	form.
8	Q The question is: Do you see anywhere that	8	BY MS. DALY:
9	he has cited to a particular medical record that	9	Q Dr. Hurst.
10	shows these failure modes that he's listed on page	10	A Can I comment that you can you could
11	1?	11	compare it to degrees.
12	A Well, not a specific citation, but he I	12	Q Okay. Degrees or percent?
13	think it's the same page that you're referring to.	13	A Degrees or percent, they are more or less
14	He says "I also reviewed the following	14	equivalent.
15	case-specific medical records and images."	15	Q Well, wait a minute. Degrees goes around
16	Q Correct. But which of those show which	16	in a circle and that's 360, and percent only has
17	failure mode, he hasn't expressed that, correct?	17	100. I'm a lawyer.
18	MR. O'CONNOR: Form.	18	A Right.
19	THE WITNESS: I need to read through them	19	Q Yeah, we won't we won't waste time on
20	all to see what's said against each of them.	20	that.
21	Well, there's one that says "Chest X ray	21	A Sorry, I was thinking of radians, radians,
22	with IVC filter being at the L2 lower vertebral	22	which you then have to convert.
23	body and vertical, mostly with 4 percent tilt to	23	Q I will not put my math up to yours.
24	the left."	24	A You're I stand corrected. I stand
25	BY MS. DALY:	25	corrected.
-		_	
1	Page 267 Q Right, so on page on page 7 he's got a	1	Page 269  Q That was pretty smart of me just then.
2	bullet point that says that, correct?	2	Okay. Hurst, let's look at Hurst, page 5,
3	A Well, I don't know if I have to count	3	and if you look under B he's talking about the
4	to get	4	implant or Dr. Avino positioning it, the filter in
5	Q I know.	5	her case, with the superior tip at L2-L3. Do you
6	A to whether it's page 7.	6	see that?
7	Q Sorry about that.	7	A Yes.
l		8	
8	A But it's it's just above a section that's entitled "Case-specific"	9	` ' '
Į.	-	ı	also talks about the filter fragment in the right
10	Q Correct.	10	middle lobe of the pulmonary artery?
11	A "opinions regarding Doris Jones."	11	A Yes.
12	Q Correct.	12	Q Okay. All right. Okay. Beyond what's in
13	A And then there's IV there's it	13	Dr. Hurst and Dr. Muehrcke's reports, did you do
14	doesn't say what it is but he does refer	14	anything else to verify whether there were
15	specifically in the next line to "IVC filter with a	15	perforations, for example, in the case of
16	right mid-lung metallic object near the right	16	Ms. Jones?
17	hilum," and then	17	MR. O'CONNOR: Form.
18	Q Uh-huh.	18	THE WITNESS: Well, I read some medical
19	A the next one down referring to PA and	19	records but I didn't directly look at them to
20	lateral films which show the right middle lung	20	well, I did, I looked for whether they mentioned
21	metallic device.	21	things like something outside of the vena cava, but
22	Q Okay.	22	I didn't I didn't correlate what was what I
23	A So there are some there's some	23	saw with what was in the Muehrcke and Hurst
23		0.4	
24	specificity.	24	reports.
		25	BY MS. DALY:

_	In Re: Bard IVC Fin	1	1044010 21401111)
-	Page 270		Page 272
1	Q So do you know if she had perforations or	1	whether she experienced Valsalva movements?
2	not?	2	MR. O'CONNOR: Form.
3	A I don't know.	3	THE WITNESS: I have no information about
4	Q Okay.	4	that.
5	A Actually, I should look at this again to	5	BY MS. DALY:
6	see what it says in the summary.	6	Q Do you know how her history of GI bleeds
7	Q Sure.	7	and being on anti-coagulants may have impacted the
8	A So there's no mention of perforations, so	8	filter?
9	it appears that there's no record of perforation.	9	A Since I'm not a medical expert, I have no
10	Q All right. And you read off a moment ago	10	view on that.
11	that in Dr. Muehrcke's report he shows the tilt of	11	Q Okay. And once again in this report,
12	4 percent or 4 degrees, whatever	12	Dr. Hurst and Dr. Muehrcke both say they took into
13	A 4 percent.	13	consideration the plaintiffs comorbidities,
14	Q He says percent. Okay.	14	medical history and preexisting conditions with
15	Do you know well, I'm assuming you	15	respect to her. Do you know what interpretation,
16	haven't talked to Dr. Muehrcke about what he means	16	if any, they made of those things?
17	by 4 percent?	17	A No.
18	A No, I haven't.	18	MR. O'CONNOR: Object to form.
19	Q Whether it's our 4 degrees or it's	19	THE WITNESS: I don't know.
20	something else?	20	BY MS. DALY:
21	A No, I haven't talked to him.	21	Q And you did not take those into
22	Q Okay. Do you know that physicians who use	22	consideration yourself in drawing your conclusions?
23	IVC filters typically don't consider a tilt to an	23	MR. O'CONNOR: Objection. Form.
24	IVC filter to be clinically significant unless it's	24	THE WITNESS: No, I did not.
25	15 degrees or above?	25	BY MS. DALY:
	Page 271		Page 273
1	MR. O'CONNOR: Form.	1	Q Okay. Now, in Mrs. Jones' case, did you
2	THE WITNESS: I don't know that for a fact	2	read the deposition of her retrieving doctor, a
3	myself.	3	Dr. Kristin Nelson?
4	BY MS. DALY:	4	A No, I did not.
5	Q Okay. And then again, other than	5	Q Do you know if she verified whether there
6	Muchreke's information about a 4 percent tilt, do	6	was migration of the filter?
7	you have any other information of her filter	7	MR. O'CONNOR: Form.
8	progressing beyond that to a greater degree of tilt	8	THE WITNESS: No, I don't I don't know
9	at any time that she had it?	9	that.
10	A Not to my recollection.	10	BY MS. DALY:
11	Q And again with her, you have not gotten	11	Q Or perforation?
12	any information that gives you data on what the	12	A I don't know. I don't know.
13	quality of her vena cava tissue is or its firmness	13	Q Okay.
14	or its flexibility?	14	A I don't know what she said.
15	A No.	15	Q Okay. About any complication
16	MR. O'CONNOR: Form.	16	A About anything.
17	BY MS. DALY:	17	Q that she saw?
18	Q And you have not had any information about		A Yeah, about anything.
19	what her blood flow was?	19	Q You do know that she saw a fracture
20	A No.	20	because she made an attempt to remove the piece?
21	Q Her respiratory rate	21	A Well, I may have observed that in the
22	A No.	22	medical records, but I don't recall exactly whether
23	Q while she had the filter?	23	it was this case or another one.
		A 4	0. 01
24 25	A No.  Q What information any information about	24 25	Q Okay.  A Of course it may have been someone else,

Robert McMeeking , Ph.D. In Re: Bard IVC Filters Products Liability

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	Page 274	1	Page 276
1	another physician involved if it was another case.	1	Q So without those pieces of evidence, we
2	Q All right. Now, also in Mrs. Jones'	2	we don't have the physical evidence from the
3	report on page 1 at your bullet your last bullet	3	fragment or the filter to help us look at causes of
4	there, bullet 5, you say that "Ms. Jones' Eclipse	4	the fracture, true?
5	filter was used as intended, properly implanted,	5	MR. O'CONNOR: Form.
6	and there was no other causes of failures of that	6	THE WITNESS: Without either the filter or
7	filter."	7	the fragment, that information's not available. Or
8	Again with her, what did you mean for her	8	cannot be obtained safely.
9	when you said the filter was used as intended?	9	BY MS. DALY:
10	A I mean it was implanted in her vena cava	10	Q So again in your report, you concluded
11	and it functioned as a filter within her vena cava.	11	that events that occurred with Ms. Jones' filter
12	Q And you didn't try to make any assessment	12	were consistent with the kinds of failures that
13	whether her previous bleeding issues or anything	13	you've discussed in your prior reports and in this
14	made her a good candidate for the filter?	14	deposition today, correct?
15	A I did not make that assessment.	15	A That's correct.
16	Q Okay. Did you make any assessment of	16	Q Okay. And again, you have not attempted
17	whether it was properly implanted or you just	17	to do any modeling or calculations specific to
18	accepted the doctor's statements on that?	18	Ms. Jones that might include consideration of her
19	A I relied on	19	vena cava size, respiratory rate, Valsalva
20	MR. O'CONNOR: Object to form.	20	experience, vena cava or surrounding organ tissue
21	THE WITNESS: Dr. Hurst and	21	quality or stiffness, existence or extent of
22	Dr. Muehrcke in on that question.	22	perforations, existence of or distance of any
23	BY MS. DALY:	23	alleged caudal migration, the degree of tilt of her
24	Q And then with respect to your comment "no		filter, whether the filter was catching clots at
25	other causes of failures of the filter were	25	the time, in order to calculate any strains that
	Page 275		Page 277
1	present," you did not, in making that in giving	1	might have been occurring in her filter at any
2	that opinion, you did not investigate anything	2	location at any time, true?
3	specific to Ms. Jones' anatomy or medical		
		3	MR. O'CONNOR: Object to the form of the
4	conditions, medical history, true?	4	question.
5	A Correct.	4 5	question.  THE WITNESS: I have not done any
5 6	A Correct. MR, O'CONNOR: Form.	4 5 6	question.  THE WITNESS: I have not done any calculations related to those phenomena that you
5 6 7	A Correct. MR, O'CONNOR: Form. BY MS. DALY:	4 5 6 7	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.
5 6 7 8	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody	4 5 6 7 8	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:
5 6 7 8 9	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody has sent you a report showing that they have	4 5 6 7 8 9	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:  Q So we'll go to
5 6 7 8 9	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody has sent you a report showing that they have examined the removed filter, correct?	4 5 6 7 8 9	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:  Q So we'll go to MR. O'CONNOR: What is the time, by the
5 6 7 8 9 10 11	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody has sent you a report showing that they have examined the removed filter, correct? A That's correct.	4 5 6 7 8 9 10	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:  Q So we'll go to  MR. O'CONNOR: What is the time, by the way?
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5 6 7 8 9 10 11 12 13	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody has sent you a report showing that they have examined the removed filter, correct? A That's correct. Q And assuming that the piece is in situ and we don't have the filter, we can't look on either the filter or the piece to determine what it might	4 5 6 7 8 9 10 11 12 13 14	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:  Q So we'll go to  MR. O'CONNOR: What is the time, by the way?  BY MS. DALY:  Q Ms. Kruse.  THE VIDEOGRAPHER: It's 4:12.
5 6 7 8 9 10 11 12 13 14	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody has sent you a report showing that they have examined the removed filter, correct? A That's correct. Q And assuming that the piece is in situ and we don't have the filter, we can't look on either the filter or the piece to determine what it might tell us about cause of fracture or contribution	4 5 6 7 8 9 10 11 12 13 14	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:  Q So we'll go to MR. O'CONNOR: What is the time, by the way?  BY MS. DALY:  Q Ms. Kruse. THE VIDEOGRAPHER: It's 4:12. MR. O'CONNOR: No, how long have we been
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody has sent you a report showing that they have examined the removed filter, correct? A That's correct. Q And assuming that the piece is in situ and we don't have the filter, we can't look on either the filter or the piece to determine what it might tell us about cause of fracture or contribution to to the fracture, correct? MR. O'CONNOR: Object to the form. THE WITNESS: I need to look at what I say. So I don't know where the filter is. It was removed successfully, but otherwise I don't	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:  Q So we'll go to MR. O'CONNOR: What is the time, by the way?  BY MS. DALY:  Q Ms. Kruse. THE VIDEOGRAPHER: It's 4:12. MR. O'CONNOR: No, how long have we been on? THE VIDEOGRAPHER: We've been on the record for 5 hours and 36 minutes. MR. O'CONNOR: Thanks.  BY MS. DALY: Q And just you don't have to go off the
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody has sent you a report showing that they have examined the removed filter, correct? A That's correct. Q And assuming that the piece is in situ and we don't have the filter, we can't look on either the filter or the piece to determine what it might tell us about cause of fracture or contribution to to the fracture, correct? MR. O'CONNOR: Object to the form. THE WITNESS: I need to look at what I say. So I don't know where the filter is. It was removed successfully, but otherwise I don't know where it is. And as of the time of writing of	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:  Q So we'll go to MR. O'CONNOR: What is the time, by the way?  BY MS. DALY:  Q Ms. Kruse. THE VIDEOGRAPHER: It's 4:12. MR. O'CONNOR: No, how long have we been on? THE VIDEOGRAPHER: We've been on the record for 5 hours and 36 minutes. MR. O'CONNOR: Thanks.  BY MS. DALY: Q And just you don't have to go off the record for this, the reason I'm going through each
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A Correct. MR. O'CONNOR: Form. BY MS. DALY: Q And in her case, has do you nobody has sent you a report showing that they have examined the removed filter, correct? A That's correct. Q And assuming that the piece is in situ and we don't have the filter, we can't look on either the filter or the piece to determine what it might tell us about cause of fracture or contribution to to the fracture, correct? MR. O'CONNOR: Object to the form. THE WITNESS: I need to look at what I say. So I don't know where the filter is. It was removed successfully, but otherwise I don't know where it is. And as of the time of writing of	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	question.  THE WITNESS: I have not done any calculations related to those phenomena that you describe.  BY MS. DALY:  Q So we'll go to MR. O'CONNOR: What is the time, by the way?  BY MS. DALY:  Q Ms. Kruse. THE VIDEOGRAPHER: It's 4:12. MR. O'CONNOR: No, how long have we been on? THE VIDEOGRAPHER: We've been on the record for 5 hours and 36 minutes. MR. O'CONNOR: Thanks.  BY MS. DALY: Q And just you don't have to go off the record for this, the reason I'm going through each

# Robert McMeeking, Ph.D. In Re: Bard IVC Filters Products Liability

1 M Thank you for clarifying that. Thank you. 2 Q It's not that I'm just done and I'm water 3 hammering you. 4 Okay. So we're going to Ms. Kruse. In 5 your report on Ms. Kruse on page I, in the bottom 6 paragraph you say "I determined to a reasonable 7 degree of engineering and scientific certainty that 8 Ms. Kruse's G2 filter experienced all of the 9 failure modes consistent with defects inherent in 1 that filter," correct? 11 A That's correct. 12 Q And then on page I at bullet 3 you talk 13 about the failure modes, and you've listed filter 14 tilled in excess of I5 degrees and embedded in the 15 wall; 5 of 12 struts of her IVC filter perforated 16 the vena cava with involvement of vital organs, 17 vessels and structures; filter caudally migrated 18 approximately 5 centimeters; and filter not 19 retrieved and remains in place. 20 A That's correct. 21 Q All right. And what did you do to 22 determine that Ms. Kruse's filter had experienced 23 each of those events? 24 A I read the medical records that I had 25 available to me, I read Dr. Hurst's report and 26 A Yes, I relied principally on those two 27 reports. 28 Q All right. Let's look at Hurst on her 29 first. Page 5. Section D. If you would, go back 10 a page to page 4 and look at under "Case 11 Summary," paragraph 3A and B. Dr. Hurst is 12 reporting that a G2 filter was placed on July 8, 13 2009 in Ms. Kruse, orrect?  1	_	In Re: Bard IVC Fill	VIS 1	Toddots Elability
2 A That's correct. 3 hammering you. 4 Okay. So we're going to Ms. Kruse. In 5 your report on Ms. Kruse on page 1, in the bottom 6 paragraph you say "I determined to a reasonable 7 degree of engineering and scientific certainty that 8 Ms. Kruse's GZ filter experienced all of the 9 failure modes consistent with defects inherent in 10 that filter," correct? 11 A That's correct. 12 Q And then on page 1 at bullet 3 you talk 13 about the failure modes, and you've listed filter 15 wall; 5 of 12 struts of her IVC filter perforated 16 the vena cava with involvement of vital organs, 17 vessels and structures; filter caudally migrated 18 approximately 5 centimeters; and filter not 19 retrieved and remains in place. 20 A That's correct. 21 Q All right. And what did you do to 22 determine that Ms. Kruse's filter had experienced 23 each of those events? 24 A Tread the medical records that I had 25 available to me, I read Dr. Hurst's report and 26 available to me, I read Dr. Hurst's report and 27 Page 279 28 A Ves. 29 Q Nay. And would — do you rely on 29 Dr. Hurst and Dr. Muehrcke's report, 29 Dr. Hurst and Dr. Muehrcke's report principally for 29 Dr. Hurst and Dr. Muehrcke's report principally for 29 Dr. Hurst and Dr. Muehrcke's report principally for 20 per first. Page 5. Section D. If you would, go back 21 a page to page 4 and look at — under "Case 21 that Dr. Hurst is commenting on it in this imaging 22 in 2011? 3 Dr. Hurst and Dr. Muehrcke's report principally for 3 Dr. Hurst and Dr. Muehrcke's report principally for 4 Page 279 4 A Yes, I relied principally on those two 7 reports. 8 Q All right. Let's look at Hurst on her 9 first. Page 5. Section D. If you would, go back 2 a page to page 4 and look at — under "Case 2 Il Summary," paragraph 3A and B. Dr. Hurst is 2 reporting that a GZ filter was placed on fully 8, 3 2009 in Ms. Kruse, correct? 4 A Yes. 5 Page 279 5 Page 279 6 A Yes. 6 Q All right. Let's look at Hurst on her 9 first. Page 5. Section D. If you would, go back 3 a page to page 4 and look at — under "Case 4 D				Page 280
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A A According to this information.	2			
5 your report on Ms. Kruse on page I, in the bottom 6 paragraph you say "I determined to a reasonable degree of engineering and scientific certainty that 8 Ms. Kruse's G2 filter experienced all of the 9 failure modes consistent with defects inherent in 1 that filter," correct. 10	3	= -	3	
6 paragraph you say "I determined to a reasonable degree of engineering and scientific certainty that Ms. Kruse's GZ fitter experienced all of the failure modes consistent with defects inherent in that filter," correct?  10 that filter, "correct?  11 A That's correct.  12 Q And then on page I at bullet 3 you talk about the failure modes, and you've listed filter tilted in excess of 15 degrees and embedded in the wall; 5 of 12 struts of her IVC filter perforated the vena cava with involvement of vital organs, 17 vessels and structures; filter caudally migrated 3 approximately 5 centimeters; and filter not retrieved and remains in place.  12 Q All right. And what did you do to determine that Ms. Kruse's filter had experienced each of those events?  13 A That's correct.  14 A Yes.  15 A Yes.  16 Q And he identifies perforation with a vertebral body and an iliac artery wall of some struts there?  18 Q Mnt he identifies perforation with a vertebral body and an iliac artery wall of some struts there?  19 A Which which line is that?  10 In Ithe failure modes, and you've listed filter that wall; 5 of 12 struts of her IVC filter perforated the wall; 5 of 12 struts of her IVC filter perforated the wall; 5 of 12 struts of her IVC filter perforated the wall; 5 of 12 struts of her IVC filter perforated the vena cava with involvement of vital organs, 17 vessels and structures; filter caudally migrated a provided and remains in place.  12 A That's correct.  13 A Yes.  14 A Yes.  15 A Which which line is that?  15 In Diverded and remains in place.  16 A That's correct.  17 A Yes.  18 Q And he also gives his grading, II or III on that, right?  20 A That's correct.  21 Q Okay. And would - do you rely on  22 A Yes, I relied more than't a wettebral body and an iliac artery wall of some struts there?  23 A That's correct.  24 A That's correct.  25 Q And he also gives his grading, II or III on that, right?  26 A That's correct.  27 A No, I don't.  28 Q Okay. Do you have any information that that in the report to see whether th	4		4	<del>-</del>
7   degree of engineering and scientific certainty that   8   Ms. Kruse's G2 filter experienced all of the   failure modes consistent with defects inherent in   10   that filter," correct?   11   A   That's correct.   12   Q   And then on page 1 at builet 3 you talk   13   about the failure modes, and you've listed filter   14   titled in excess of 15 degrees and embedded in the   14   titled in excess of 15 degrees and embedded in the   15   wall, 5 of 12 strust of her IVC filter perforated   16   the vena cava with involvement of vital organs,   17   vessels and structures; filter caudally migrated   18   approximately 5 centimeters; and filter not   19   retrieved and remains in place.   20   A   That's correct.   21   Q   All right. And what did you do to   determine that Ms. Kruse's filter had experienced   22   each of those events?   23   A   read the medical records that I had   25   available to me, I read Dr. Hurst's report and   25   The medical records that I had   25   available to me, I read Dr. Hurst's report and   26   A   Yes.   16   A   Yes.   27   A   Yes.   28   A   Ves.   29   A	5	·	1	· · · · · · · · · · · · · · · · · · ·
8 Ms. Kruse's G2 filter experienced all of the 9 failure modes consistent with defects inherent in 10 that filter," correct. 11 A That's correct. 12 Q And then on page 1 at bullet 3 you talk 13 about the failure modes, and you've listed filter 14 tilted in excess of 15 degrees and embedded in the 15 walt, 5 of 12 struts of her IVC filter perforated 16 the vena cava with involvement of vital organs, 17 vessels and structures; filter caudally migrated 18 approximately 5 centimeters; and filter not 19 retrieved and remains in place. 10 Q All right. And what did you do to 20 determine that Ms. Kruse's filter had experienced 21 each of those events? 22 ach of those events? 23 A No, I don't. 24 A I read the medical records that I had 25 available to me, I read Dr. Hurst's report and 25 available to me, I read Dr. Hurst's report and 26 Dr. Hurst and Dr. Muchrcke's report. 27 Q Okay. And would — do you rely on 28 Dr. Hurst and Dr. Muchrcke's report principally for 29 the being able to say that her filter experienced these 29 things? 20 A Yes, I relied principally on those two 20 reports. 21 Q All right. Let's look at Hurst on her 22 first. Page 5. Section D. If you would, go back 23 agap to page 4 and look at — under "Case 24 A Yes, the date against that paragraph is 25 the 8th of July 2009. 26 Q Yes, And then if you look at his comments 27 in D where he is referencing a CT of abdomen and 28 pelvis 3-7-11 — 29 Q — he is commenting on "The tip of filter 20 Q - he is commenting on "The tip of filter 21 caudally migrated 5 centimeters." 22 Q So at least based on Dr. Hurst's 25 Q of a head. 26 Q Gapahead. 27 A — answer the question. 28 Q Gapahead. 29 Q Fach, go ahead. 20 Q fach aleast five minutes 20 Q fach and Orconnors. 21 Q Gapahead. 22 Gapahead. 23 Q Gapahead. 24 A — answer the question. 25 Q Gapahead. 26 Q Gapahead. 27 A — answer the question. 28 Q Gapahead. 29 Q Fach, go ahead. 20 Q fach acad. 21 Q Gapahead. 22 Q Fach, go ahead. 23 Q Gapahead. 24 A — answer the question. 25 Q Gapahead. 26 Q Fach and Dr. Hurst's there			1	
failure modes consistent with defects inherent in that filter," correct?  10 that filter," correct?  11 A That's correct.  12 Q And then on page 1 at bullet 3 you talk about the failure modes, and you've listed filter titled in excess of 15 degrees and embedded in the wall; 5 of 12 struts of her IVC filter perforated the vena cava with involvement of vital organs, vessels and structures; filter caudally migrated approximately 5 centimeters; and filter not retrieved and remains in place.  10 A That's correct.  11 Q All right. And what did you do to determine that Ms. Kruse's filter had experienced each of those events?  12 A I read the medical records that I had available to me, I read Dr. Hurst's report and  13 Dr. Hurst and Dr. Muehrcke's report, 2 Q Okay. And would — do you rely on 3 Dr. Hurst and Dr. Muehrcke's report, 2 Page 279 to being able to say that her filter experienced these things?  15 A Yes, 1 relied principally on those two reports.  16 Q All right. Let's look at Hurst on her first. Page 5. Section D. If you would, go back a page to page 4 and look at — under "Case 11 Summary," paragraph 3A and B. Dr. Hurst is 12 reporting that a G2 filter was placed on July 8, 12009 in Ms. Kruse, correct?  18 Q And he identifities perforation with a vertebral body and an iliac actery wall of some struts there?  19 A Yes. A Yes. and then in fyou look at one mode in the title end wall, will in the stand? (I mich wall, in the perforation of struts.  19 A Yes. A Yes. and then if you look at his comments in plevis 3-7-11.  10 Q - he is commenting on "The tip of filter caudally migrated 5 centimeters."  21 Q So at least based on Dr. Hurst's  22 A Yes. Q So at least based on Dr. Hurst's  23 A Well, I really should read what's in here before I. Q Go ahead.  24 A Yes. A Grown in the identifies perforation with a trutter and brink in the strutt. In the filter and wall, will in the strutts.  25 A Yes. And then in you look at sumder in the strutts.  26 A Yes, 1 relied principally on those two control in this imaging in 2011	7		7	
10 that filter," correct? 11 A That's correct. 12 Q And then on page 1 at bullet 3 you talk about the failure modes, and you've listed filter tilted in excess of 15 degrees and embedded in the twena cava with involvement of vital organs, tessels and structures; filter caudally migrated 18 approximately 5 centimeters; and filter not retrieved and remains in place. 19 A That's correct. 20 A Il right. And what did you do to deach of those events? 21 Q All right. And what did you do to deach of those events? 22 determine that Ms. Kruse's filter had experienced each of those events? 23 available to me, I read Dr. Hurst's report and 12 bailed by a will be being able to say that her filter experienced these finings? 25 A Yes, I relied principally on those two reports. 26 Q All right. Let's look at Hurst on her fights. Page 5. Section D. If you would, go back a page to page 4 and look at under "Case 11 Summary," paragraph 3A and B. Dr. Hurst is 11 the 8th of July 2009. 26 Q Yes. And the identifies perforation with a vertebral body and an iliac artery wall of some strust there? 27 A Which which line is that? 28 A Which which line is that? 29 A That's correct. 20 A robe also gives his grading, II or III on that, right? 21 A That's correct. 21 Q And he also gives his deactification is of rade and view there. 22 A Ness. 23 Q So at least based on Dr. Hurst's report and I work that. 24 A Yes. 25 That's correct. 26 Q And he also gives his grading, II or III on that, right? 27 A Yes. 28 Q And he also gives his grading, II or III on that, she's talking about different perforating strusts. 29 A Nes. 20 Q And he also gives his grading, II or III on that, she's talking about different perforating strusts. 20 Q And he also gives his grading, II or III on that, right? 20 Q In in that, right? 21 A Yes. 22 Q And he also gives his grading, II or III on that, she's talking about different perforating strusts. 21 Q And he also gives his grading, II or III on that, she's talking about different perforating strusts. 22 A Yes, and	1		1 -	•
11 A That's correct. 12 Q And then on page 1 at bullet 3 you talk about the failure modes, and you've listed filter titled in excess of 15 degrees and embedded in the wall; 5 of 12 struts of her IVC filter perforated the vena cava with involvement of vital organs, it vessels and structures; filter caudally migrated approximately 5 centimeters; and filter not retrieved and remains in place. 19 A That's correct. 20 A That's correct. 21 Q All right. And what did you do to determine that Ms. Kruse's filter had experienced each of those events? 22 A A I read the medical records that I had available to me, I read Dr. Hurst's report and 25 available to me, I read Dr. Hurst's report and 26 Dr. Muchrcke's report. 27 Q Okay. And would — do you rely on 3 Dr. Hurst and Dr. Muchrcke's report to see whether that's mentioned elsewhere is things? 28 A Yes, I relied principally on those two reports. 39 Q All right. Let's look at Hurst on her first. Page 5. Section D. If you would, go back a page to page 4 and look at — under "Case 11 Summany," paragraph 3A and B. Dr. Hurst is report to gage 4 and look at — under "Case 11 Summany," paragraph 3A and B. Dr. Hurst is report ting that a G2 filter was placed on July 8, 13 2009 in Ms. Kruse, correct? 30 Q Yes. And then if you look at his comments in plevis 3-7-11 — 19 A Yes. 30 Q — he is commenting on "The tip of filter caudally migrated 5 centimeters." 31 Q — he is commenting on "The tip of filter caudally migrated 5 centimeters." 32 Q So at least based on Dr. Hurst's	1		1	
12   Q And then on page 1 at bullet 3 you talk about the failture modes, and you've listed filter tilted in excess of 15 degrees and embedded in the swall; 5 of 12 struts of her IVC filter perforated the vena cava with involvement of vital organs, 12 vessels and structures; filter caudally migrated approximately 5 centimeters; and filter not retrieved and remains in place. 20 A That's correct. 21 Q All right. And what did you do to determine that Ms. Kruse's filter had experienced 22 each of those events? 24 A I read the medical records that I had 25 available to me, I read Dr. Hurst's report and 25 m. Hurst and Dr. Muehrcke's report. 26 Q Okay. And would—do you rely on 3 Dr. Hurst and Dr. Muehrcke's report principally for 4 being able to say that her filter experienced these things? 4 A Yes, I relied principally on those two reports. 3 Q All right. Let's look at Hurst on her 9 first. Page 5. Section D. If you would, go back 10 a page to page 4 and look at — under "Case 11 Summary," paragraph 3A and B. Dr. Hurst is report tight at a G2 filter was placed on July 8, 13 2009 in Ms. Kruse, correct? 14 A Yes, the date against that paragraph is the 8th of July 2009. 4 Yes. 20 Q — he is commenting on "The tip of filter 21 caudally migrated 5 centimeters." 21 Q P and would read what's in here before I— A Yes. 22 Q So at least based on Dr. Hurst's 23 A Yes. 24 Q So at least based on Dr. Hurst's 24 C Go ahead. 4 A — answer the question. 25 Go ahead. 4 A — answer the question. 26 Go ahead. 4 A — answer the question. 27 Go ahead. 4 A — answer the question. 27 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the question. 29 Go ahead. 4 A — answer the que	10	•	,	• •
about the failure modes, and you've listed filter lifted in excess of 15 degrees and embedded in the twens cava with involvement of vital organs, vessels and structures; filter caudally migrated approximately 5 centimeters; and filter not retrieved and remains in place.  A That's correct.  A That's correct.  A Tread the medical records that I had ease of those events?  A I read the medical records that I had available to me, I read Dr. Hurst's report and Page 279  Dr. Muehrcke's report.  Q Q Okay. And would — do you rely on a Dr. Hurst and Dr. Muehrcke's report to being able to say that her filter experienced these things?  A Yes, I relied principally on those two reports.  Q All right. Let's look at Hurst on her a page to page 4 and look at — under "Case reports.  Q All right. Let's look at Hurst on her a page to page 4 and look at — under "Case in D. My would a page to page 4 and look at — under "Case in D. My would have a page to page 4 and look at — under "Case in D. My would have a page to page 4 and look at — under "Case in D. Where he is referencing a CT of abdomen and la pelvis 3-7-11 — la A Yes.  Q G he is commenting on "The tip of filter cadadlly migrated and provided in the tilted in the ti	11		1	· · · · · · · · · · · · · · · · · · ·
tilted in excess of 15 degrees and embedded in the wall; 5 of 12 struts of her IVC filter perforated the vena cava with involvement of vital organs, 17 vessels and structures; filter caudally migrated approximately 5 centimeters; and filter not retrieved and remains in place.  19 A That's correct.  20 A That's correct.  21 Q All right. And what did you do to determine that Ms. Kruse's filter had experienced each of those events?  22 A I read the medical records that I had available to me, I read Dr. Hurst's report and  Page 279  1 Dr. Muehrcke's report.  2 Q Okay. And would — do you rely on 2 Dr. Hurst and Dr. Muehrcke's report principally for 4 being able to say that her filter experienced these 5 things?  6 A Yes, I relied principally on those two reports.  8 Q All right. Let's look at Hurst on her 9 first. Page 5. Section D. If you would, go back 10 a page to page 4 and look at — under "Case 11 Summary," paragraph 3A and B. Dr. Hurst is 11 the 8th of July 2009.  18 Yes, the date against that paragraph is the 8th of July 2009.  19 A Yes.  20 Q — he is commenting on "The tip of filter 21 caudally migrated d site of vital organs. In the wind provided in the wind in the wind provided in the wall, is and x, he's talking about different perforating struts.  10 A Yes.  11 A Yes.  22 A A That's correct.  23 Q And he also gives his grading, II or III on that, right?  24 A That's correct.  25 Q And you do not know what Dr. Hurst's ow definition is of Grade II or III?  26 A That's correct.  27 Q And you do not know what Dr. Hurst's ow definition is of Grade II or III?  28 A No, I don't.  29 A No, I don't.  21 A No, I don't.  21 A No, I don't.  22 A Well, I would have to read through the report to see whether that's mentioned elsewhere in the report see whethe	12		1	struts there?
15 wall; 5 of 12 struts of her IVC filter perforated 16 the vena cava with involvement of vital organs, 17 vessels and structures; filter caudally migrated 18 approximately 5 centimeters; and filter not 19 retrieved and remains in place. 20 A That's correct. 21 Q All right. And what did you do to 22 determine that Ms. Kruse's filter had experienced 23 each of those events? 24 A I read the medical records that I had 25 available to me, I read Dr. Hurst's report and 26 available to me, I read Dr. Hurst's report and 27 Page 279 28 I Dr. Muehrcke's report. 29 Q Okay. And would — do you rely on 30 Dr. Hurst and Dr. Muehrcke's report principally for 40 being able to say that her filter experienced these 41 that Dr. Hurst is commenting on it in this imaging 42 in 2011? 43 A Yes, I relied principally on those two 45 reports. 46 A Yes, I relied principally on those two 47 reports. 48 Q All right. Let's look at Hurst on her 49 first. Page 5. Section D. If you would, go back 10 a page to page 4 and look at — under "Case 11 Summary," paragraph 3A and B. Dr. Hurst is 12 reporting that a G2 filter was placed on July 8, 13 2009 in Ms, Kruse, correct? 14 A Yes, the date against that paragraph is 15 the 8th of July 2009. 16 Q Yes. And then if you look at his comments 17 in Dwhere he is referencing a CT of abdomen and 18 Q And he also gives his grading, II or III 19 on that, right? 20 A That's correct. 21 Q And you do not know what Dr. Hurst's own definition is of Grade II or III? 22 A No, I don't. 23 A Well, I would have any information that 24 Ms. Kruse's filter has tilted more than the amount 25 that Dr. Hurst is commenting on it in this imaging 26 in 2011? 27 A No, I don't. 28 A No, I don't. 29 A Well, I would have to read through the 29 reports. 20 Q All right. Let's look at Hurst on her 20 Q All right. Let's look at Hurst on her 21 a Yes, the date against that paragraph is 22 the struts. 23 A Yes. 24 A Yes. 25 Q - he is commenting on "The tip of filter 26 Caudally migrated 5 centimeters." 27 A Yes. 28 Q So at least based o	13	· · · · · · · · · · · · · · · · · · ·	13	
16 the vena cava with involvement of vital organs, vessels and structures; filter caudally migrated approximately 5 centimeters; and filter not retrieved and remains in place.  20 A That's correct. 21 Q All right. And what did you do to determine that Ms. Kruse's filter had experienced each of those events? 22 each of those events? 23 A I read the medical records that I had available to me, I read Dr. Hurst's report and 25 available to me, I read Dr. Hurst's report and  Page 279 1 Dr. Muehrcke's report. 2 Q Okay. And would do you rely on 3 Dr. Hurst and Dr. Muehrcke's report principally for 4 being able to say that her filter experienced these things? 6 A Yes, I relied principally on those two 7 reports. 8 Q All right. Let's look at Hurst on her 9 first. Page 5. Section D. If you would, go back 10 a page to page 4 and look at under "Case 11 Summary," paragraph 3A and B. Dr. Hurst is reporting that a G2 filter was placed on July 8, 13 2009 in Ms. Kruse, correct? 11 A Yes. 12 Q And he also gives his grading, II or III on that, right?  A That's correct. 21 Q And you do not know what Dr. Hurst's own definition is of Grade II or III? 22 A Yes. 23 Q Okay. Do you have any information that Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has tilted more than the amount Ms. Kruse's filter has	14		14	
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20	1	pelvis 3-7-11	18	A Well, I really should read what's in here
21 caudally migrated 5 centimeters."   21 A answer the question.   22 A Yes.   22 Q Go ahead.   23 Q So at least based on Dr. Hurst's   23 MR. O'CONNOR: Let's take five minutes	19		19	
22 A Yes. 23 Q So at least based on Dr. Hurst's 22 Q Go ahead. 23 MR. O'CONNOR: Let's take five minutes	20	Q he is commenting on "The tip of filter	20	, -
23 Q So at least based on Dr. Hurst's 23 MR. O'CONNOR: Let's take five minutes	21	caudally migrated 5 centimeters."	21	A answer the question.
_	22	A Yes.	22	Q Go ahead.
24 materials, somewhere between implant in July of '09 24 while he's doing that, please.	23	Q So at least based on Dr. Hurst's	23	MR. O'CONNOR: Let's take five minutes
	24	materials, somewhere between implant in July of '09	24	while he's doing that, please.
25 and this CT in March of '11 the filter caudally 25 MS, DALY: Uh-huh,	25	and this CT in March of '11 the filter caudally	25	MS, DALY: Uh-huh.

Robert McMeeking , Ph.D.
In Re: Bard IVC Filters Products Liability

	In Re: Bard IVC FIR	VI3 1	1 Toddots Estability
	Page 282		Page 284
1	THE VIDEOGRAPHER: We're going off the	1	Q Okay. Do you have any information either
2	record at 1617.	2	on your own or from Dr. Hurps Hurst or anything
3	(Brief pause.)	3	that Dr. Muehrcke cites to that Ms. Kruse has a
4	THE VIDEOGRAPHER: We're back on the	4	fracture?
5	record at 1618. This is the end of Media No. 4.	5	A I need to look again at my report.
6	We are going off the record at 1618.	6	Q Sure.
7	(Recess taken.)	7	A See what I say.
8	(Whereupon, Deposition Exhibits 7A, 7B,	8	I make no mention of fracture, so that
9	8A, 8B, 9A, 9B, 10A, 10B, 11A and 11B	9	would indicate that there is no information
10	were marked for identification by the	10	indicating a fracture has taken place.
11	Court Reporter.)	11	Q Okay. And with Ms. Kruse, you have not
12	(Record read as follows:	12	received any information about the quality,
13	"And do you have any information	13	flexibility, firmness, or lack thereof, of her vena
14	about any changes in the number	14	cava tissue?
15	or extent of perforation of	15	A Correct.
16	struts in her filter as described	16	Q Or of the stiffness, lack of stiffness, or
17	by Dr. Hurst here.")	17	makeup of her vertebral bodies or iliac artery
18	THE VIDEOGRAPHER: This is the beginning	18	vessel?
19	of Media No. 5. We are back on the record at 1625.	19	MR. O'CONNOR: Form.
20	THE WITNESS: Well, having read the	20	THE WITNESS: No specific information on
21	report, I realize that Dr. Hurst says that it was	21	that.
22	observed that the filter tilted to more than 15	22	BY MS. DALY:
23	degrees at some stage.	23	Q You don't have any information about what
24	So correcting what I said before, there is	24	her blood flow was?
25	information that says that the tilting preceded	25	A No information on that.
	Page 283		Page 285
1	beyond 15 degrees. I have the comment on	1	MR. O'CONNOR: Form.
2	perforation is is not there to allow me to	2	BY MS. DALY:
3	sorry, there is no comment on the perforation in a	3	Q Or what her typical respiratory rate was?
4	manner that allows me to say whether perforation	4	A I have no information on that.
5	increased in number in terms of the number of limbs	5	Q Do you have any information on whether she
6	involved or progressed further than it was in the	6	experienced Valsalva movements and to what extent?
7	observation at the 7th of March 2011.	7	A I have no information on that.
8	BY MS. DALY:	8	Q Do you know whether her diabetes, anemia,
9	O All right. Let's look at Dr. Muehrcke.	9	use of anti-coagulants or her cancer issues played
10	page I. In that first paragraph he describes the	10	any role in impacting the filter?
11	following failure modes: Caudal migration, tilt,	11	A Since I'm not a medical expert, I can't
12	fracture, perforation of the vena cava, penetration	12	make an assessment of that.
13	of adjacent organs and structures, and	13	Q Dr. Hurst and Dr. Muehrcke in this report
14	irretrievability.	14	also said they took into consideration the
15	MR, O'CONNOR: Where where are you	15	plaintiff's comorbidities, medical history and
16	looking at? I'm sorry.	16	preexisting conditions. Again, you do not know
17	MS. DALY: Page 1 of Muehrcke. We're not	17	what interpretation of those they did; is that
18	in Hurst, we're on Muchroke.	18	correct?
19	MR. O'CONNOR: Are you talking about	19	A That's correct, I don't know what
20	Kruse?	20	interpretation they placed on that.
21	MS. DALY: Yeah,	21	Q And you did not interpret or rely on
22	MR. O'CONNOR: Okay. Thank you.	22	anything about her comorbidities, medical history
23	BY MS. DALY:	23	or preexisting conditions in your opinions, true?
23 24		23 24	A That's correct.
	Q Do you see where he's said that? A Oh. Yes. Yes.	25	Q On page 1 of your report, and it's bullet
25		7. 1	A AND DAYS I OF VIOLE COOKS, 2001 II S DITIES

Robert McMeeking, Ph.D.
In Re: Bard IVC Filters Products Liability

	III NO. Daild I VO I III	T	
	Page 286	1	Page 288
I	4, you you say that her "G2 filter was used as	1	MR. O'CONNOR: Form.
2	intended, properly implanted, and there were no	2	THE WITNESS: That has not been done, so
3	other causes of failures of that filter."	3	the information directly from the fracture surface
4	With respect to Ms. Kruse, are you giving	4	has not been obtained. But, nevertheless, we still
5	any opinion with respect to whether she was an	5	know to a reasonable degree of of engineering
6	appropriate candidate for the filter?	6	probability that if it has fractured as in that
7	A I'm not giving any opinion on that.	7	as in the other cases which have fractured, that
8	MR. O'CONNOR: Form.	8	the cause is very probably fatigue fracture.
9	BY MS. DALY:	9	BY MS. DALY:
10	Q Are you aware that she had had recurrent	10	Q But there are other causes that you all
11	DVT and PE with anti-coagulants prescribed before	11	have talked about, Dr. Richie and you have talked
12	the time that she was implanted with the filter?	12	about, that initiate fracture besides like
13	A I may have been aware of that from reading	13	perforation, right?
14	her medical records, but I don't recall.	14	MR. O'CONNOR: Object to the form.
15	Q With respect to the comment on "proper	15	BY MS. DALY:
16	implant," would you defer to Dr. Hurst or Muehrcke	16	Q Let me restate that.
17	or the medical records about whether that was a	17	A I
18	properly done implant?	18	Q There are causes of fracture that might
19	A Well, I would defer to Drs. Hurst and	19	include contact wire to wire that you might be able
20	Muehrcke and the physician who prepared the medical	20	to see on surfaces, true?
21	records.	21	A But but that would initiate fatigue
22	Q Okay. With respect to your comment "no	22	fracture.
23	other causes of the failures of the filter," did	23	Q Right. Well, everything to have a
24	you investigate anything specific to Ms. Hyde's	24	fatigue fracture, you've got to have fatigue,
25	anatomy or medical conditions?	25	right?
	Page 287		Page 289
1	MR. O'CONNOR: Kruse.	1	A Yes. Correct.
2	MS. DALY: Oh. Sorry.	2	Q Okay. So in every case, if it is
3	MR. O'CONNOR: That's all right.	3	determined that a fracture was fatigued as opposed
4	BY MS. DALY:	4	to a cutting a cutting of the wire or something
5	Q Did you investigate anything specific to	5	like that, there's going to be some cause for
6	Ms. Kruse's anatomy, medical conditions, history or	6	fatigue, correct?
7	comorbidities?	7	A Okay. The the statement I made is that
8	A No, I did not.	8	it is a fatigue mechanism that causes the fracture,
9	Q If there was any fracture in this filter,	9	and that fatigue mechanism will go back to some
10	you're not aware of anyone having been able to	10	source that initiates the fatigue cracking and the
11	inspect the filter or the fractured limb, correct?	11	fatigue damage that the filter is experiencing,
12	MR. O'CONNOR: Form.	12	although filter although just cycling the
13	THE WITNESS: Repeat the repeat the	13	material through a range of strains will cause
14	question, please.	14	fatigue damage within the material, so even if
15	BY MS. DALY:	15	there are not features present in the material that
16	Q Yeah.	16	you can identify specifically as associated with
17	You don't know if if anyone if there	17	the design of the filter or its manufacturing.
18	is a fracture in this filter, you are not aware of	18	So my point is simply that it is fatigue
19	anyone who has looked at either the filter or the	19	failure that is most likely to have caused the
20	fragment, true?	20	fractures that we're looking at in all of these
21	A That's correct.	21	cases, if there are fractures
22	Q So to the extent to the extent that	22	Q Okay.
23	looking at the filter or the fragment might tell us	23	A in any given case.
24	something about causation of the fracture, as far	24	Q And you will agree with me that with
	-		
25	as you know that has not been done?	25	respect to any given person, there are numerous

Robert McMeeking , Ph.D. In Re: Bard IVC Filters Products Liability

1 permutations of conditions that the filter can be in? 2 in? 3 A There are many configurations it can be in juyes. 4 in juyes. 5 Q And those can be impacted by patient-specific things? 7 A That's correct. 8 Q And they can be dependent on — well, I'll juyst leave it at that, patient-dependent things, you agree with that? 11 MR. O'CONNOR: Form. 12 THE WITNESS: I agree, but these patient-dependent things are entirely predictable in terms of what will happen over a population of patients who are implanted with vena cava filters. 16 BY MS. DALY: 17 Q But what's not predictable is whether life with the was a perforation and Ms. Smith might not? 18 MR. O'CONNOR: Form. 19 person what complication they're going to have with the medical device, true? 10 person what complication they're going to have with the medical device, true? 11 person what complication they're going to have with the medical device, true? 12 person what complication they're going to have with the medical device, true? 13 per submiring the information you need to do that is the challenge — 14 person what complication they're going to have with the medical device, true? 15 BY MS. DALY: 16 Person what complication they're going to have with the medical device, true? 17 person what complication they're going to have with the medical device, true? 18 Q Yeah. 29 Q Kay. And now with respect to Ms. Kruse, a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava involvement in vital organs and structures adj to the vena cava, her filter tilted approximately 20 degrees and embedded to the wall of the IVC, a structure of the filter at any time in vena cava filters. 18 PMS. DALY: 19 person what complication they're going to have with the medical device, true? 20 Q Right. You can't ever predict for a given in the medical device, true? 31 person what complication they're going to have with the medical device, true? 42 person what complication they re going to have with the		<del></del>	Т	<del></del>
2 im? 3 A There are many configurations it can be in, yes. 5 Q And those can be impacted by 6 patient-specific things? 7 A That's correct. 8 Q And they can be dependent on — well, I'll just leave it at that, patient-dependent things, 10 you agree with that? 11 MR. O'CONNOR: Form. 12 THE WITNESS: I agree, but these 13 patient-dependent things are entirely predictable in terms of what will happen over a population of 15 patients who are implanted with vena cava filters. 16 BY MS. DALY: 17 Q But what's not predictable is whether 18 Ms. Kruse will have a perforation and Ms. Smith 19 might not? 20 MR. O'CONNOR: Form. 21 THE WITNESS: Well, without the relevant 1 information, that — it's not possible to make that 2 prediction. 24 BY MS. DALY: 25 Q Right. You can't ever predict for a given 1 person what complication they're going to have with 2 the medical device, true? 3 MR. O'CONNOR: Form. 4 THE WITNESS: Well, I think you can, but the medical device, true? 5 MR. O'CONNOR: Form. 6 Page 291 Person what complication they're going to have with 2 the medical device, true? 8 Q Yeah. 9 A — rather than the actual carrying out of 10 the prediction. 11 Q Okay. And now with respect to Ms. Kruse, 11 Q Okay. And now with respect to Ms. Kruse, 12 think this is where I was, you have not attempted 10 do any models or calculations specific to her as a 1 a patient, for example, using as a variable her 10 to do any models or calculations specific to her as 1 a patient, for example, using as a variable her 10 to do any models or calculations specific to her as 1 a patient, for example, using as a variable her 10 to do any models or calculations specific to her as 1 a patient, for example, using as a variable her 10 to do any models or calculations specific to her as 1 a patient, for example, using as a variable her 10 to do any models or calculations specific to her as 1 a patient, for example, using as a variable her 10 to do any models or calculations specific to her as 1 a patient, for example, using as a variable her 10 to do any mo	,	Page 290	1	Page 292
degree of engineering and scientific certainty Ms. Mulkey's Eclipse filter experienced all th failure modes consistent with defects inherent that filter," correct? A That's correct.  A That's correct. A That's correct.  A That's correct. A That's correct.  A A combination of the medical records a in the challenge of the stabling arms of filter filter wing and structures and involvement in vital organs and structures and the events of the vents of the vents cave and the correct in saying the vents of the vents of the vents of the vents of the v		-	1	
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11  Q Okay. And now with respect to Ms. Kruse, 12  I think this is where I was, you have not attempted 13  to do any models or calculations specific to her as 14  a patient, for example, using as a variable her 15  vena cava size, her respiratory rate, any Valsalva 16  experience she had, the quality of her vena cava 17  tissue or surrounding organ or vessel tissue, the 18  extent of her perforations, the degree of any tilt 19  that she had, the extent to which the filter was 20  catching clots, to calculate specific strains in 21  any portion of the filter at any time in her? 22  A That's correct. 23  MR. O'CONNOR: Hurst and Muehrcke? 16  MR. O'CONNOR: Object to the form of question. 18  Q Which of them indicates that they have identified a fracture? 19  A I need to look through those reports to any portion of the filter was 20  Catching clots, to calculate specific strains in 21  BY MS. DALY: 22  A That's correct. 23  A I'm on Hurst, yes.	9	· -		· · · · · · · · · · · · · · · · · · ·
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15 vena cava size, her respiratory rate, any Valsalva 16 experience she had, the quality of her vena cava 17 tissue or surrounding organ or vessel tissue, the 18 extent of her perforations, the degree of any tilt 19 that she had, the extent to which the filter was 20 catching clots, to calculate specific strains in 21 any portion of the filter at any time in her? 22 A That's correct. 23 MR. O'CONNOR: Form. 25 Q Which of them indicates that they have 16 identified a fracture? 17 A I need to look through those reports to - 18 Q Sure. 19 A determine that. 20 MR. O'CONNOR: Go ahead. 21 BY MS. DALY: 22 Q And let me help you. Are you on Hurst 23 A I'm on Hurst, yes.	1			
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17 tissue or surrounding organ or vessel tissue, the 18 extent of her perforations, the degree of any tilt 19 that she had, the extent to which the filter was 20 catching clots, to calculate specific strains in 21 any portion of the filter at any time in her? 22 A That's correct. 23 MR. O'CONNOR: Form. 21 In need to look through those reports to - 18 Q Sure. 19 A determine that. 20 MR. O'CONNOR: Go ahead. 21 BY MS. DALY: 22 Q And let me help you. Are you on Hurst. 23 A I'm on Hurst, yes.	13 14	to do any models or calculations specific to her as a patient, for example, using as a variable her	14	BY MS. DALY:
18 extent of her perforations, the degree of any tilt 19 that she had, the extent to which the filter was 20 catching clots, to calculate specific strains in 21 any portion of the filter at any time in her? 22 A That's correct. 23 MR. O'CONNOR: Form. 28 G Sure. 29 And Let me help you. Are you on Hurst A I'm on Hurst, yes.	13 14 15	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva	14 15	BY MS. DALY:  Q Which of them indicates that they have
19 that she had, the extent to which the filter was 20 catching clots, to calculate specific strains in 21 any portion of the filter at any time in her? 22 A That's correct. 23 MR. O'CONNOR: Form. 29 A determine that. 20 MR. O'CONNOR: Go ahead. 21 BY MS. DALY: 22 Q And let me help you. Are you on Hurst. 23 A I'm on Hurst, yes.	13 14 15 16	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva	14 15 16	BY MS. DALY:  Q Which of them indicates that they have identified a fracture?
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21 any portion of the filter at any time in her? 22 A That's correct. 23 MR. O'CONNOR: Form. 21 BY MS. DALY: 22 Q And let me help you. Are you on Hurst 23 A I'm on Hurst, yes.	13 14 15 16 17 18	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava tissue or surrounding organ or vessel tissue, the	14 15 16 17	BY MS. DALY:  Q Which of them indicates that they have identified a fracture?  A I need to look through those reports to Q Sure.
22 A That's correct. 22 Q And let me help you. Are you on Hurst 23 MR. O'CONNOR: Form. 23 A I'm on Hurst, yes.	13 14 15 16 17 18	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava tissue or surrounding organ or vessel tissue, the extent of her perforations, the degree of any tilt that she had, the extent to which the filter was	14 15 16 17 18 19	BY MS. DALY: Q Which of them indicates that they have identified a fracture? A I need to look through those reports to Q Sure. A determine that.
23 MR. O'CONNOR: Form. 23 A I'm on Hurst, yes.	13 14 15 16 17 18 19	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava tissue or surrounding organ or vessel tissue, the extent of her perforations, the degree of any tilt that she had, the extent to which the filter was	14 15 16 17 18 19 20	BY MS. DALY: Q Which of them indicates that they have identified a fracture? A I need to look through those reports toQ Sure. A determine that.
1	13 14 15 16 17 18 19 20	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava tissue or surrounding organ or vessel tissue, the extent of her perforations, the degree of any tilt that she had, the extent to which the filter was catching clots, to calculate specific strains in	14 15 16 17 18 19 20 21	BY MS. DALY:  Q Which of them indicates that they have identified a fracture?  A I need to look through those reports to Q Sure.  A determine that.  MR. O'CONNOR: Go ahead.  BY MS. DALY:
24 BY MS. DALY: 24 Q Look at page 6, G, F and G.	13 14 15 16 17 18 19 20 21	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava tissue or surrounding organ or vessel tissue, the extent of her perforations, the degree of any tilt that she had, the extent to which the filter was catching clots, to calculate specific strains in any portion of the filter at any time in her?	14 15 16 17 18 19 20 21	BY MS. DALY:  Q Which of them indicates that they have identified a fracture?  A I need to look through those reports to Q Sure.  A determine that.  MR. O'CONNOR: Go ahead.  BY MS. DALY: Q And let me help you. Are you on Hurst?
	13 14 15 16 17 18 19 20 21 22	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava tissue or surrounding organ or vessel tissue, the extent of her perforations, the degree of any tilt that she had, the extent to which the filter was catching clots, to calculate specific strains in any portion of the filter at any time in her?  A That's correct.	14 15 16 17 18 19 20 21	BY MS. DALY:  Q Which of them indicates that they have identified a fracture?  A I need to look through those reports to Q Sure.  A determine that.  MR. O'CONNOR: Go ahead.  BY MS. DALY:  Q And let me help you. Are you on Hurst?  A I'm on Hurst, yes.
25 Q All right. Let's talk about Ms. Mulkey. 25 A Yes, it says in F that that the that	13 14 15 16 17 18 19 20 21 22 23 24	to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava tissue or surrounding organ or vessel tissue, the extent of her perforations, the degree of any tilt that she had, the extent to which the filter was catching clots, to calculate specific strains in any portion of the filter at any time in her?  A That's correct.  MR. O'CONNOR: Form.  BY MS. DALY:	14 15 16 17 18 19 20 21 22 23 24	BY MS. DALY:  Q Which of them indicates that they have identified a fracture?  A I need to look through those reports to Q Sure.  A determine that.  MR. O'CONNOR: Go ahead.  BY MS. DALY: Q And let me help you. Are you on Hurst? A I'm on Hurst, yes. Q Look at page 6, G, F and G.

# Robert McMeeking , Ph.D. In Re: Bard IVC Filters Products Liability

	In Re. Dard IVC Fin		
	Page 294	1	Page 296
1	it was demonstrated that there was additional	1	THE WITNESS: I'm not aware of that.
2	failure to the filter with an internal fracture of	2	BY MS. DALY:
3	the 11:00 stabilizing arm.	3	Q You noted in your report a foreign what
4	Q And what does Dr. Muehrcke say about	4	did you say? The something about a foreign
5	fracture, other than on on page 1 he says that	5	object that has yet to be located?
6	the failure modes were caudal migration, tilt,	6	A Can you find the
7	fracture, perforations of the vena cava and	7	Q Yeah, let me
8	perforation	8	A the line.
9	A I would have to look at the report to see	9	Q I think it's in your final bullet point
10	that.	10	there. Yeah.
11	Q Yeah. Okay.	11	A Final bullet point on page
12	A On the second to last page.	12	Q No, it's the third bullet point. The last
13	Q Uh-huh.	13	line of the third bullet point.
14	A In the first full paragraph it says, in	14	A Oh. So it says "One of the stabilizing
15	the sentence that begins one, two, three, four,	15	arms of her filter fractured and has yet to be
16	five, six, seven seventh line, "This risk of	16	located." Is that the
17	harm is ongoing as Ms. Mulkey is exposed to further	17	Q Yeah.
18	and progressive perforation of her vena cava,	18	A That's what you're referring to?
19	penetration of adjacent vital organs and	19	Q And and you're basing that on Hurst and
20	structures, additional strut fracture, and	20	Muchrcke's saying that there's been a fracture and
21	embolization of the existing fracture fragment."	21	it hasn't been located?
22	And then there's more words in that sentence, too.	22	A That's correct.
23	Q Okay. Does he does he cite to where	23	Q Okay. I mean, I'm making you haven't
24	he's he's seeing this alleged strut fracture or	24	looked at imaging and said "Oh, there's no fracture
25	progression of perforation?	25	located"?
	Page 295		Page 297
1	MR. O'CONNOR: Object to the form of the	1	A No, I haven't done that.
2	question.	2	Q Okay. And with respect to Ms. Mulkey, do
3	THE WITNESS: He does not specifically	3	you have any information about her tissue quality,
4	cite any observation, but nevertheless, I find the	4	firmness, flexibility, or lack thereof, in the vena
5	report very informative because of the information	5	cava?
6	which is within it.	6	MR. O'CONNOR: Form.
7	BY MS. DALY:	7	THE WITNESS: No, I have no such
8	Q If	8	information.
9	A As I do the report by Dr. Hurst and all	9	BY MS. DALY:
10	the other reports in the Bellwether cases.	10	Q Do you have any information about her
11	Q Have you read any of Bard's case-specific	11	her tissue quality, flexibility, firmness, or lack
12	medical experts?	12	thereof, in any of her adjacent organs or vessels?
13	A No, I have not.	13	A No, I have no specific information about
14	Q Do you know that the doctors don't agree	14	that.
15	about there being a fracture in Ms. Mulkey?	15	Q Did you have any information about what
16	A I'm not aware of that.	16	her blood flow rate was?
17	MR. O'CONNOR: Object to the form of the	17	A No, I have no such information.
18	question.	18	Q Or about her respiratory rate?
19	BY MS. DALY:	19	A I have no such information.
20	Q Do you know that the doctors don't agree	20	Q Or about information any information
21	about there being a fracture in Ms. Kruse?	21	about her experience of Valsalva movements or how
22	MR. O'CONNOR: Object	22	often?
23	THE WITNESS: I'm not	23	A No, I have no such information.
24	MR. O'CONNOR: to the form of the	24	Q Dr. Hurst and Dr. Muehrcke both said in
25	question.	25	their reports that they took into consideration

# Robert McMeeking , Ph.D. In Re: Bard IVC Filters Products Liability

	Page 298	1	Page 300
l	plaintiff's comorbidities, medical history and	1	BY MS. DALY:
2	preexisting conditions. Do you know what	2	Q If there was a fracture in her filter, do
3	interpretation they have made of those items?	3	you agree that we do you have any information
4	A No	4	that anybody has been able to examine the filter
5	MR. O'CONNOR; Form.	5	itself or this alleged fragmented piece?
6	THE WITNESS: I do not know.	6	MR. O'CONNOR: Form.
7	BY MS. DALY:	7	THE WITNESS: It appears that both the
8	Q And you have not taken into consideration	8	filter itself and the fragment are at the time
9	any comorbidities, medical history or preexisting	9	of writing of this document, were still in
10	conditions in Ms. Mulkey in making your opinions in	10	Ms. Mulkey, and, therefore, it's not been possible
11	the case?	11	to examine those pieces of the filter.
12	MR. O'CONNOR: Object	12	BY MS. DALY:
13	THE WITNESS: No	13	Q Okay. You conclude that the events that
14	MR. O'CONNOR: to the form of the	14	occurred in Ms. Mulkey's filter are consistent with
15	question.	15	the kinds of failures that we've discussed in this
16	THE WITNESS: I have not.	16	deposition and in your reports in the litigation,
17	BY MS. DALY:	17	correct?
18	Q In your report, page 1, in your last	18	A That's correct.
19	bullet point, you say "The filter was used as	19	Q All right. But you've not attempted to
20	intended, properly implanted, and there were no	20	model or do any calculations of Ms. Mulkey's vens
21	other causes for failure."	21	cava size, her respiratory rate, Valsalva
22	With respect to Ms. Mulkey, do you have	22	experience, her vena cav cava or surrounding
23	any information about why her doctors made the	23	organ and vessel tissue or stiffness, nor have you
24	decision to implant her with the IVC filter?	24	done any modeling of any the extent of her
25	MR. O'CONNOR: Form.	25	perforations, the degree of any tilt that her
	Page 299		Page 301
1	THE WITNESS: Well, I've read some medical	1	filter experienced, the extent to which it was
2	records and the information may be in there, but	2	catching clots to calculate what strains may have
3	I I don't recall the reasons from that.	3	heen in play on Me Mulkey's filter at any time
		,	been in play on Ms. Mulkey's filter at any time
4	BY MS. DALY:	4	MR. O'CONNOR: Form.
5	Q Do you recall that she had recurrent DVT	4 5	MR. O'CONNOR: Form. BY MS. DALY:
5	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the	4 5 6	MR. O'CONNOR: Form. BY MS. DALY: Q while it's been in situ?
5 6 7	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?	4 5 6 7	MR. O'CONNOR: Form.  BY MS. DALY:  Q while it's been in situ?  A I have
5 6 7 8	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall	4 5 6 7 8	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form.
5 6 7 8 9	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall that specific information.	4 5 6 7 8 9	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form. THE WITNESS: I have not done anything or
5 6 7 8 9	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall that specific information.  Q With respect to your comment on proper	4 5 6 7 8 9	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form. THE WITNESS: I have not done anything of those issues specific to Ms. Mulkey.
5 6 7 8 9 10	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall that specific information.  Q With respect to your comment on proper implantation, do you defer to either Hurst,	4 5 6 7 8 9 10 11	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form. THE WITNESS: I have not done anything of those issues specific to Ms. Mulkey. BY MS. DALY:
5 6 7 8 9 10 11 12	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall that specific information.  Q With respect to your comment on proper implantation, do you defer to either Hurst, Muehrcke or other medical specialists to give the	4 5 6 7 8 9 10 11	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form. THE WITNESS: I have not done anything of those issues specific to Ms. Mulkey.  BY MS. DALY: Q Okay. Let me look at my notes.
5 6 7 8 9 10 11 12	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall that specific information.  Q With respect to your comment on proper implantation, do you defer to either Hurst, Muehrcke or other medical specialists to give the opinion whether it was a proper implant?	4 5 6 7 8 9 10 11 12 13	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form. THE WITNESS: I have not done anything of those issues specific to Ms. Mulkey.  BY MS. DALY: Q Okay. Let me look at my notes. You cannot say to a reasonable degree of
5 6 7 8 9 10 11 12 13	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall that specific information.  Q With respect to your comment on proper implantation, do you defer to either Hurst,  Muehrcke or other medical specialists to give the opinion whether it was a proper implant?  A I defer to Drs. Hurst, Muehrcke and the	4 5 6 7 8 9 10 11 12 13 14	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form. THE WITNESS: I have not done anything of those issues specific to Ms. Mulkey.  BY MS. DALY: Q Okay. Let me look at my notes. You cannot say to a reasonable degree of engineering probability that any given Bard filter
5 6 7 8 9 10 11 12 13 14	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall that specific information.  Q With respect to your comment on proper implantation, do you defer to either Hurst, Muehrcke or other medical specialists to give the opinion whether it was a proper implant?  A I defer to Drs. Hurst, Muehrcke and the implanting implanting physician.	4 5 6 7 8 9 10 11 12 13 14 15	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form. THE WITNESS: I have not done anything of those issues specific to Ms. Mulkey.  BY MS. DALY: Q Okay. Let me look at my notes. You cannot say to a reasonable degree of engineering probability that any given Bard filter in any given patient will have any complication?
5 6 7 8 9 10 11 12 13 14 15	Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?  A I may have read that, but I don't recall that specific information.  Q With respect to your comment on proper implantation, do you defer to either Hurst, Muehrcke or other medical specialists to give the opinion whether it was a proper implant?  A I defer to Drs. Hurst, Muehrcke and the implanting implanting physician.  Q Okay. With respect to your comment "no	4 5 6 7 8 9 10 11 12 13 14 15 16	MR. O'CONNOR: Form.  BY MS. DALY: Q while it's been in situ? A I have MR. O'CONNOR: Objection. Form. THE WITNESS: I have not done anything of those issues specific to Ms. Mulkey.  BY MS. DALY: Q Okay. Let me look at my notes. You cannot say to a reasonable degree of engineering probability that any given Bard filter in any given patient will have any complication? MR. O'CONNOR: Form.
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Robert McMeeking, Ph.D.
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July 6, 2017

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	Page 306		Page 300
1	calculations to understand and make a come to	1	Q And when you talk about worst-case
2	opinions on the other models that I did not do	2	scenario, is that a standard that engineers are
3	specific calculations for.	3	required to follow?
4	Q And could you tell us, you described some	4	A Yes, in dealing with this kind of problem,
5	through, but tell us the types of calculations, the	5	engineers are expected and required to identify the
6	types of analyses, that you performed in arriving	6	worst-case conditions and then take that into
7	at your opinions in this case.	7	consideration when assessing the performance of
8	A Well, I did Euler-Bernoulli beam	8	their design and the consequences of of the
9	calculations to look at the strains induced in the	9	design.
10	limbs of filters as the vena cava expands and	10	Q Now I want to I want to move around a
11	contracts. I looked at some finite element	11	little bit. Well, let me ask you about
12	calculations for the same problem. I carried out	12	calculations and analyses. You talked about the
13	finite element calculations to look at the	13	ones you've performed. In your work in this case,
14	phenomenon of tilt in of the filter in the vena	14	did you look at and review the types of
15	cava.	15	calculations, the engineering analyses, that Bard
16	Q To arrive at the opinions, was it	16	performed?
17	necessary for you to engage in any type of testing	17	A I reviewed finite element calculations
18	such as bench testing?	18	that they performed.
19	A No, it wasn't necessary for me to carry	19	Q And do you have an opinion about whether
20	out any bench testing.	20	those were sufficient or adequate?
21	Q Why?	21	A Almost all of them were inadequate for
22	A Because I had information that was	22	various reasons.
23	available to me from tests carried out by Bard and,	23	Q What were the reasons, among the reasons,
24	in addition, I had my engineering analysis which	24	please?
25	enabled me to assess the phenomenon that would take	25	A Well, some of the reasons were that it was
	Page 307		Page 309
1	place in the filters in the circumstances that I	1	clear that they were not carried out in a reliable
2	described.	2	manner and the results looked inconsistent with
3	Q Your report and you were asked some	3	each other within sets of calculations and
4	questions today about Bard testing and Bard	4	comparing some calculations from one set with
5	analyses, so let's just talk about testing. Have	5	calculations from another, and that this was not
6	you reviewed the testing, bench testing, that Bard	6	scrutinized in a way that would enable the
7	did of its filters?	7	discrepancies to be understood so that the
8	A I've reviewed a lot of the bench testing	8	calculations could be carried out in a reliable and
9	that Bard did of the filters.	9	accurate manner.
10	Q And what is your opinion about the	10	In addition, the assumptions that went
11	bench the testing, including bench testing, that	11	into the calculations were almost always not
12	Bard did?	12	appropriate for the calculations that were being
13	A That the testing that they undertook was	13	done, such as the constraints on the motion of the
14	inadequate and that it was not at a level that	14	components of the filter and the way that the
15	would enable them to understand the failures that	15	calculation was carried out to ensure that accurate
16	are likely to occur in the filter.	16	results were obtained.
17	Q Explain your opinion, if you will.	17	Q If the tests the analyses that Bard
18	A Well, for example, they didn't identify	18	performed were did take the step to be reliable
19	the worst-case conditions that the filter would	19	and were accurate, as you suggest they were not, do
20	experience, and they didn't test the filter in	20	you have an opinion whether Bard would have known
21	conditions that would reproduce such worst-case	21	that its filters were predictably going to fail?
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78 (Pages 306 - 309)

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A Yes.

MS. DALY: Object to form.

THE WITNESS: Those results, when

accurately computed, would have revealed that there

conditions.

the inadequacy of testing?

A Yes, they do.

Q Do your reports detail your opinions about

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١.	Page 310		Page 312
1	were failure modes that would be predictable when		dwell time?
2	the filters were implanted in patients.	2	A May I look at the report?
3	BY MR. O'CONNOR:	3	Q Please.
4	Q Does that include migration?	4	A So that's Exhibit No. 12 and so in the
5	A That includes migration.	5	abstract it says "The mean filter dwell time at
6	Q Fracture?	6	trieval" "at retrieval was 200.8 days and the
7	A Fracture.	7	range was 5 to 736."
8	Q Tilt?	8	Q And and was there a limit in the number
9	A Tilt.	9	of filters that were studied, patients?
10	Q And perforation?	10	A There were 200 patients that were studied.
11	A And perforation.	11	Q Now, you mentioned something earlier in
12	Q You were asked questions about the Denali filter. You have evaluated the Denali filter?	12 13	your testimony, you talked about the filters, the
13		14	Recovery, the G2, the G2X, the Eclipse, the Meridian and then the Denali. You mentioned that
14		i	
15 16	of its features that make it similar and different from other models in the in the Bard line of	15 16	these filters were permanent filters?
1	filters.	17	A The Recovery through the Denali were
17 18		ı	optional filters, which means that they can be
19	Q And have you determined that the design of the Denali fil filter will cause it to	19	implanted as permanent filters with an option to retrieve.
20		20	
l	predictably fail?  A Yes.	21	Q And was your point earlier that being
21 22		22	permanent, that the design should be one that will not fail after it's implanted in a patient?
23	Q And what is the based what is that opinion based upon?	23	A Yes. Yes. My
24	A Because it is very similar in shape and	24	•
25	configuration to the other filters which also	25	MS. DALY: Object to form.  THE WITNESS: The important point is if a
25	<del></del>	25	
١.	Page 311		Page 313
1		1 1	Change to the control of the control
	which themselves are subject to failures, and the	1	filter is to be used as a permanent filter, it
2	analysis that I've done on the various Bard filters	2	should be able to deal with the lifetime
2 3	analysis that I've done on the various Bard filters indicates that such failure modes will be present	2	should be able to deal with the lifetime environment that that filter will experience during
2 3 4	analysis that I've done on the various Bard filters indicates that such failure modes will be present in them. And because of the similarities that the	2 3 4	should be able to deal with the lifetime environment that that filter will experience during implantation.
2 3 4 5	analysis that I've done on the various Bard filters indicates that such failure modes will be present in them. And because of the similarities that the Denali has with the ones that I analyzed, one will	2 3 4 5	should be able to deal with the lifetime environment that that filter will experience during implantation.  BY MR. O'CONNOR:
2 3 4 5 6	analysis that I've done on the various Bard filters indicates that such failure modes will be present in them. And because of the similarities that the Denali has with the ones that I analyzed, one will expect the same kind of failures to occur in the	2 3 4 5 6	should be able to deal with the lifetime environment that that filter will experience during implantation. BY MR. O'CONNOR: Q And when
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Robert McMeeking , Ph.D. In Re: Bard IVC Filters Products Liability

	M 1407 But 1 7 0 1 110	l	D 216
,	Page 314	1	Page 316  A Yeah, I finally found the paper and was
1 2	longer the filter is in a patient, the greater is the likelihood that failure will occur.	2	able to make use of the information within that
3	MR. O'CONNOR: Thank you.	3	paper.
4	I just got a message that the phone has	4	Q All right. And assuming that was the
5	been disconnected.	5	paper that Dr. Briant was referring to, did he cite
6	MS. DALY: Maybe it has a length of time	6	it correctly?
7	that it will do a conference call. Probably	7	A He if it was the paper he meant to
8	that's probably it. We're probably over the time	8	cite, he did not cite it correctly.
9	that the thing allows.	9	Q And where was he incorrect?
10	MR. O'CONNOR: I wonder how we can	10	A Well, you when I say "cite," I mean
11	reconnect the people in.	11	provide the location where the paper is to be
12	THE COURT REPORTER: Can we go off the	12	found. Are you asking is that can you
13	record?	13	clarify the question?
14	MR. O'CONNOR: Yes.	14	Q Did he represent the article the
15	THE VIDEOGRAPHER: We're going off the	15	information in that paper correctly?
16	record at 1705.	16	A Well, he stated that it showed that a Cook
17	(Recess taken.)	17	filter would significantly impede the contraction
18	THE VIDEOGRAPHER: We are back on the	18	of the vena cava during the relevant motion that
19	record at 1706.	19	was imposed on it, and that seemed to, in my in
20	BY MR. O'CONNOR:	20	my interpretation "significant" means that the
21	Q Now, in your work, you have analyzed each	21	compression would be much less than the compression
22	of the failure modes, correct?	22	that would occur in the absence of the filter;
23	A That's correct.	23	whereas, the data in the paper shows that the
24	Q You were asked some questions and you	24	compression of the vena cava at the filter is
25	talked about Dr. Briant's reports, correct?	25	two-thirds that which occurs in the absence of the
	Page 315		Page 317
1	A That's correct.		
	A That's correct.	1	filter.
2		2	And to me, that's that's a I note
2			
	Q And you testified about some assumptions	2	And to me, that's that's a I note
3	Q And you testified about some assumptions that he made regarding the vena cava filter, true?	2	And to me, that's that's a I note that that's a there's a reduction in the
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q And you testified about some assumptions that he made regarding the vena cava filter, true?  A That's correct.  Q You were talking about a Laborda article.  Now, did Dr. Briant cite a Laborda article in his report?  A Well, he cited one Laborda article in his report, and he also cited an article that said that there were Cook filters involved in the experiment.  Q Was his citation correct?  A The citation was incorrect because he referred to the one Laborda, et al., paper that did not have any filters involved in the in the in the work, and, therefore, it was it was a mis-citation of the relevant paper.  Q When you went and did your research, did you learn about the mis-citation?  A Well, I read his report and noted that he had referenced a paper erroneously, and I then	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	And to me, that's that's a I note that that's a there's a reduction in the compression, but I would not interpret that as a significant reduction in the compression.  Q And is that consistent with the opinions that are set forth in your reports?  A Sorry, could you repeat that question.  Q Well, when you talked about today, when you talked about that the misinterpretation by Dr. Briant, have you discussed those issues in your earlier reports?  A Well, I've discussed it in that I've always taken the position that the filters will not impede the motion to any significant extent of compression of the vena cava, and so I've addressed that in various reports and rebuttals that I've provided in various cases.  Q Now, you were asked questions about a linear and nonlinear report approach, and you
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q And you testified about some assumptions that he made regarding the vena cava filter, true?  A That's correct. Q You were talking about a Laborda article. Now, did Dr. Briant cite a Laborda article in his report?  A Well, he cited one Laborda article in his report, and he also cited an article that said that there were Cook filters involved in the experiment. Q Was his citation correct? A The citation was incorrect because he referred to the one Laborda, et al., paper that did not have any filters involved in the in the in the work, and, therefore, it was it was a mis-citation of the relevant paper. Q When you went and did your research, did you learn about the mis-citation?  A Well, I read his report and noted that he had referenced a paper erroneously, and I then tried to find the paper that would be consistent	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	And to me, that's that's a I note that that's a there's a reduction in the compression, but I would not interpret that as a significant reduction in the compression.  Q And is that consistent with the opinions that are set forth in your reports?  A Sorry, could you repeat that question.  Q Well, when you talked about today, when you talked about that the misinterpretation by Dr. Briant, have you discussed those issues in your earlier reports?  A Well, I've discussed it in that I've always taken the position that the filters will not impede the motion to any significant extent of compression of the vena cava, and so I've addressed that in various reports and rebuttals that I've provided in various cases.  Q Now, you were asked questions about a linear and nonlinear report approach, and you used the linear approach in your calculations; is
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q And you testified about some assumptions that he made regarding the vena cava filter, true?  A That's correct.  Q You were talking about a Laborda article.  Now, did Dr. Briant cite a Laborda article in his report?  A Well, he cited one Laborda article in his report, and he also cited an article that said that there were Cook filters involved in the experiment.  Q Was his citation correct?  A The citation was incorrect because he referred to the one Laborda, et al., paper that did not have any filters involved in the in the in the work, and, therefore, it was it was a mis-citation of the relevant paper.  Q When you went and did your research, did you learn about the mis-citation?  A Well, I read his report and noted that he had referenced a paper erroneously, and I then tried to find the paper that would be consistent with what he was saying he was citing, but at that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	And to me, that's that's a I note that that's a there's a reduction in the compression, but I would not interpret that as a significant reduction in the compression.  Q And is that consistent with the opinions that are set forth in your reports?  A Sorry, could you repeat that question.  Q Well, when you talked about today, when you talked about that the misinterpretation by Dr. Briant, have you discussed those issues in your earlier reports?  A Well, I've discussed it in that I've always taken the position that the filters will not impede the motion to any significant extent of compression of the vena cava, and so I've addressed that in various reports and rebuttals that I've provided in various cases.  Q Now, you were asked questions about a linear and nonlinear report approach, and you used the linear approach in your calculations; is that correct?

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	In Re: Bard IVC Filt	ers r	Toducts Liability
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1	material in the conditions involved.	1	calculations that I carried out, and that was
2	Q And is that the appropriate methodology	2	sufficient for me to form the opinion that I did.
3	that	3	Q All right. And I'm getting close here.
4	A That's	4	You were asked questions about opinions that you
5	Q engineers should follow?	5	have about the Simon nitinol filter, correct?
6	A That's the appropriate methodology that	6	A Correct.
7	should be followed in that case.	7	Q And you have talked about the Simon
8	Q So when you were talking about the sheath	8	nitinol in terms of it is better in terms of
9	and arm relationship, is that a linear issue?	9	failure modes than the other Bard filters; is that
10	A So can you clarify that question.	10	correct?
11	Q Well, give me examples of why linear is	11	A That's correct.
12	appropriate in your analysis.	12	Q Have you seen Bard internal documents that
13	A Oh, because in the cycling of the strains	13	indicate that the Simon nitinol filter was regarded
14	the filter experiences within the vena cava, within	14	by Bard to be a better filter in terms of failures
15	a certain range, the cycling will motivate only	15	and failure modes compared to its other models of
16	linear elastic behavior of the material in the	16	filters?
17	filter.	17	A Yes, I've seen copies of e-mails by
18	Q On this issue of the cap, is con is	18	Dr. C I can't quite say it correctly
19	contact between the cap and an arm necessary for	19	Cierrela, that refer to the Simon nitinol filter as
20	fracture?	20	a better filter than other filters in the Bard
	A No.	21	line.
21		22	Q Why were you can you explain the reason
22	Q How can a fracture related to the cap	23	that you compared the petal of the Simon nitinol
23	occur without direct contact?	24	filter to the arm of the Recovery and the G2?
24	A Well, the the fracture that I'm	25	
25	describing is one that would take place in the arm	23	A Because they are elements of the
	Page 319	_	Page 321
1	in the high strain location near the cap, but it	1	various of the two filters that play similar
2	doesn't necessarily occur exactly at where the	2	roles in the two filters.
3	wires of the limbs enter the cap. And so the	3	Q The medical articles that you've reviewed
4	fracture that takes place a little distance away	4	about the Simon nitinol filter, including the
5	from the edge of the cap will occur whether the arm	5	Poletti, have those affected your opinions at all?
6	itself is touching the cap or not in the	6	A No, they have not affected my opinions.
7	circumstances that we're describing.	7	Q Do those articles support your opinion
8	Q By the way, is it necessary for you to	8	that the Bard is a better filter I mean that the
9	look at an exemplar filter to render your opinions	9	Simon nitinol is a better filter in terms of
10	in this case?	10	failures?
11	A No, it's not.	11	A Since the Poletti article comments that
12	Q Was it necessary for you to look at	12	the Simon nitinol filter is a safe filter, I use
13	explanted filters to explain the cause of filter	13	that information in the paper to support my view
14	fractures?	14	that the Simon nitinol is a safer filter than the
15	A No, it's not.	15	other ones.
16	Q Did you use appropriate methodology and	16	Q All right. Now, let's talk about your
17	appropriate foundation to arrive at those opinions?	17	case-specific opinions. To arrive at the opinions
18	A Yes, I did.	18	you did in each of the five Bellwether cases, that
19	Q Was it necessary for you to do tests and	19	would be Booker, Jones, Kruse, Mulkey and Hyde,
20	test and look at test results in this case?	20	correct?
	A It was not necessary for me to do bench	21	A Correct.
21			
21 22	tests or any other kind of tests to come to my	22	Q Was it necessary for you to do any
	•	22 23	Q Was it necessary for you to do any calculations specific to those patients?
22	tests or any other kind of tests to come to my		• • • • • • • • • • • • • • • • • • • •

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١.	Page 322	1 .	Page 324
1	predictable failures that I identified as a	1	A Yes, that's my opinion.
2	consequence of my analysis of the Bard filters.	2	Q You don't need to know that information?
3	Q Did you follow the type of methodology	3	A I don't need to know that information.
4	that engineers should follow when they are looking	1	Q And that's something that would not be
5	at failures and failure modes of medical devices	5	necessary following the appropriate methodology
6	such as filters when you arrived at your opinions	6	that engineers follow when they arrive at their
7	in the five cases?	7	opinions
8	A Yes, I did.	8	A That's correct.
9	Q And did you rely on the work you did in	9	Q regarding failures? A That's correct.
10	your prior reports?	10	
11 12	A I did, yes.	12	Q Was it necessary for you to do specific
13	Q Does it matter to your opinions whether	13	models or calculations in any of the five Bellwether cases?
14	the Hyde filters are G2 or G2X?  A No.	14	A No.
ł		1	
15 16	•	15 16	Q A fracture is the result of fatigue? A Yes, Correct. If the process goes on
	A Because they're they're essentially similar. They have only the difference that	17	long enough, fracture is the result of that
17 18	•	18	=
19	there's a hook on the cap and there's a slight difference to the details of the shape of the cap,	19	fatigue.  Q And the same thing: To follow the
20	but the detail differences are not big enough to	20	appropriate methodology, was it necessary for you
21	make a difference to the fatigue behavior of the	21	to know anything about the tissue quality of any of
22	G2X compared to the G2 in any significant way.	22	the five Bellwether plaintiffs or their vena cava,
23	Q And Ms. Hyde had a fractured leg in the	23	their organs or blood flow or respiratory issues?
24	ventricle of her heart?	24	A No, because it's knowing, for example,
25	A I'd have to look at the reports to	25	that Bard filters are the type we're talking about
25	<u> </u>	25	······································
١.	Page 323	١.	Page 325
1	Q Could you quickly, just to verify that.	1	perforate the wall of the vena cava, and that is
2	MS. DALY: I'll stipulate to it.	2	sufficient to provide me with information that
3	BY MR. O'CONNOR:	3	allows me to come to my opinion.
4	Q And and the point is is that that	4	Q And again, are the opinions that you've
5	failure was spelled out clearly by both	5	arrived at in the five Bellwethers, as well as the
6	Dr. Muehrcke and Dr. Hurst, true?	6	opinions that you have arrived at in your MDL
8	A That's I need to look at the reports,	7	reports, opinions to a reasonable degree of
9	but yes, that's my recollection.  Q And do you need to inspect Mrs. Hyde's	8	engineering probability?
10	Q And do you need to inspect Mrs. Hyde's filter or any filter to understand how the design	9	A And reasonable degree of engineering
11	resulted in the failure mode in each of the five?	10 11	certainty, yes. Q Thank you.
12	A No, I don't need to carry out specific	ĺ	Q Inank you.
13	inspection of the filter because it's the design	12 13	FURTHER EXAMINATION
14	itself that is the cause of the dangerous failures	14	BY MS. DALY:
15	that take place.	15	Q Dr. McMeeking, to the extent that any of
16	Q Is it necessary for you in any of the five	16	the work that you have done in this case makes
17	Bellwether plaintiffs to know anything of a	17	assumptions that are inaccurate, then the outcomes
18	specific event, such as Valsalva, the size of their	18	of the calculations would be different?
19	vena cava?	19	MR. O'CONNOR: Form and foundation.
20		20	THE WITNESS: That's always the case. If
	A No, I don't need to know anything specific because the design makes it probable that there	21	· · · · · · · · · · · · · · · · · · ·
21	will be failures of filters in patients.		the assumptions are not correct, then the analysis
22	•	22	is is not relevant. Although the degree of
23	Q And is your opinion the same as it relates	23 24	relevance may depend on how poorly the assumptions have been drawn.
24	to blood flow, comorbidities and whatever and		
25	whether they have any impact?	25	BY MS. DALY:

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١.	Page 326	ı	Page 328
1	Q Right. With respect to what Mr. O'Connor	1	we've talked about today, true?
2	just asked you about, the citation by Dr. Briant to	2	A I have πot devised any such filter.
3	the Laborda paper, you don't have any reason to	3	Q And you don't know a filter on the market
4	believe that Dr. Briant purposely mis-cited the	4	ever that would that exists with a design that
5	paper, do you?	5	resolves all these complications, true?
6	A You mean mis-cited in the terms of stating	6	A I'm not aware of any such filter, although
7	what was in the paper or	7	it's it's because I don't know the attributes of
8	Q Telling you	8	all filters.
9	A where to find it?	9	Q And you just testified that you did not
10	Q Where to find it.	10	have to do bench testing here because you had Bard
11	A I have no reason I know nothing about	11	testing to review; is that what you said?
12	why it was mis-cited.	12	A That's correct.
13	Q Okay. And in fact, as we talked about	13	Q But you said that was inadequate?
14	both today, Laborda had two similar papers	14	A Yes.
15	published a year apart, right?	15	Q Okay. So in not doing your own testing
16	A I I think it's a year apart, yes,	16	and relying on inadequate testing of Bard, you have
17	that's correct.	17	no bench testing that will provide us with an
18	Q And the Laborda paper was easy to find by	18	example of a better test that Bard could have done,
19	like Googling the author's name, true?	19	true?
20	A But I didn't know it was a Laborda paper.	20	MR. O'CONNOR: Form.
21	Q Okay.	21	THE WITNESS: Can you repeat the question.
22	A And I should comment that in terms of	22	BY MS. DALY:
23	standard of work, it's it's a problem if you	23	Q Okay. Yes.
24	don't cite sources of information properly.	24	So having not done your own testing and
25	Q Right. Like Dr. Muehrcke, correct?	25	being critical of the testing that Bard did, you
	Page 327	١.	Page 329
1	MR. O'CONNOR: Object to the form of the	1	have devised no testing that you've provided to us
2	question.	2	that is an example of better tests that Bard could
3	BY MS. DALY:	3	have done?
4	Q All right. To the extent	4	MR. O'CONNOR: Form.
5	MR. O'CONNOR: Argumentative.	5	THE WITNESS: Well, I the statement I
6	BY MS. DALY:	6	made is that I re I was able to review the Bard
7	Q To the extent that you did analyses in	7	testing and that that is a contributor to my my
8	this case, you state that for those analyses you	8	assessment of the situation, but it doesn't mean
9	employed appropriate engineering principles,	9	that I would have to do further, more elaborate
10	correct?	10	bench testing or bench testing under different
11	A Correct.	11	circumstances to come to the opinions that I came
12	Q All right. And you based your opinions on	12	to in by using my calculations.
13	the calculations analyses that you have presented,	13	BY MS. DALY:
14	true correct?	14	Q And if your assumptions in your
15	A I did.	15	calculations are inaccurate, bench testing might
16	Q And you said you did not do bench testing	16	show that?
17	that went beyond the analysis, so you did not use	17	MR. O'CONNOR: Form. Foundation.
18	actual testing to determine whether your	18	THE WITNESS: Well, I I'm not sure if I
19	assumptions and the conclusions you drew from them	19	agree with that. I don't agree with that, because
20	were accurate, true?	20	if you do a calculation based on certain
21	MR. O'CONNOR: Form.	21	assumptions and then you do a bench test with the
22	THE WITNESS: That's correct.	22	same assumptions, then you're likely to get the
23	BY MS. DALY:	23	same results from a properly designed bench test.
24	Q And you have not devised a filter that you	24	BY MS. DALY:
25	claim would have resolved the various complications	25	Q But you've seen that not happen in the

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In Re: Bard IVC Filters Products Liability

_	III Re. Baid IVC File	1	
١.	Page 330		Page 332
1	world of engineering, true?	1	BY MS. DALY:
2	A That can happen too, yes.	2	Q Okay.
3	Q And you have not developed any better	3	A And I rely on papers that indicate
4	tests or different tests that Bard could have done;	4	papers and information from reports in which the
5	is that right?	5	degree of perforation at one stage is greater
6	A I've described some tests that I think	6	sorry, let me start again with that.
7	they should have done, but I've not devised a	7	So that as time passes, the degree of
8	protocol and plan for carrying those tests out.	8	perforation increases as time passes, and,
9	Q And having not done that, you have not	9	therefore, that perforation is a progressive
10	taken it further to employ those tests to determine	10	phenomenon.
11	what they would show?	11	Q What about tilt?
12	MR. O'CONNOR: Form.	12	A Again, there are reports in the literature
13	THE WITNESS: I have not.	13	and in technical reports, such as in this case,
14	BY MS. DALY:	14	that the tilt increases with time in some cases.
15	Q Okay. Now, you said that your analysis	15	Q What about migration?
16	shows that tilt, migration, fracture and	16	A I I can't comment on migration.
17	perforation are predicted based on your analysis,	17	Q And we've seen in cases that you've given
18	correct?	18	reports on in this litigation and in some of these
19	A Correct.	19 20	Bellwether cases that there appears to be no
20	Q But you will agree that the FDA recognizes	21	evidence of progression, true?
21 22	that filters can experience any of these complications, true?	22	MR. O'CONNOR: Object to the form.
23	MR. O'CONNOR: Form and foundation.	23	THE WITNESS: Can you clarify the
24	THE WITNESS: I'm aware that Dr. Briant	24	question. BY MS. DALY:
25	has written statements like that in his report.	25	
23	•	23	<del>_</del>
.	Page 331	١.	Page 333
1	BY MS. DALY:	1	We just went through some Bellwether cases
2	Q And you're just saying that because you	2	in which there was no data showing a progression
3	don't know exactly what he recognizes?	3	of perforation in some cases or a progression of tilt?
4	A I don't know exactly right. Exactly.	5	A In some cases there's no information on
5	Q All right. But having looked at the	6	
6	testing, you know that testing was submitted to	7	that, but it doesn't mean that progression didn't
7	the FDA that looked at things like migration,	l -	OCCUR.
8	fracture?	8	Q But you don't have any information to back
9	A Yes.	10	it up?  A In in certain cases there is no
10	Q Okay. And you know also that Bard listed	11	specific observation that backs that up.
11	those four complications on its instructions for	12	Q Okay. With respect to the SNF, one last
12	use as things that can happen, correct?  MR, O'CONNOR: Form. Foundation.	13	thing, the bottom line on the SNF filter is that it
14	THE WITNESS: Well, I haven't reviewed the	14	cannot be retrieved percutaneously due to a number
15	instructions for use, so I don't know that for a	15	of reasons related to its design, fair?
16	fact.	16	MR. O'CONNOR: Form.
17	BY MS. DALY:	17	THE WITNESS: It's a permanent filter,
18	Q On what literature or other information do	18	-
	7	19	yes. BY MS. DALY:
19 20	you rely on your statement to Mr. O'Connor that the end dwell time actually leads to progression of	20	Q And it and, therefore, it does not
1	failure modes?	21	provide the same benefits as the Bard retrievable
21 22	MR. O'CONNOR: Form.	22	filters in that it cannot be percutaneously
1		23	retrieved, true?
23	THE WITNESS: Well, I rely on lots of	23 24	MR. O'CONNOR: Form. Foundation.
24 25	literature in regard to the fatigue behavior of		
1.23	nitinol.	25	THE WITNESS: I'm not a medical expert, so

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July 6, 2017

	In ite. Data ive i in	Г	<u> </u>
١.	Page 334	١.	Page 336
	I can't comment on that.		Ph.D. The total number of media used was five and
2	BY MS, DALY:	2	will be retained by Veritext Legal Solutions.
3	Q You can't comment on the fact that the SNF	3	(Whereupon, at 5:29 P.M., the
4	is not readily percutaneously retrievable?	4	videotaped deposition of ROBERT M. McMEEKING
5	A No, I meant that I can't comment on	5	Ph.D. was adjourned.)
6	the benefits of having a retrievable filter.	6	_
7	That's what I meant. Because I'm not a medical	7	oOo
8	expert.	8	
9	Q Okay. We'll just leave it at the SNF you	9	
10	know is not readily percutaneously retrievable?	10	
11	A Correct. I agree.	11	
12	Q All right. Thank you very much.	12	
13		13	
14	FURTHER EXAMINATION	14	
15	BY MR. O'CONNOR:	15	
16	Q Just to clarify, the calculations you've	16	
17	done in this case and and the assessments you've	17	
18	done, you followed the appropriate methodology,	18	
19	correct?	19	
20	A Correct.	20	
21	Q Does that methodology require you to do	21	
22	bench testing?	22	
23	A No.	23	
24	Q And in terms of Bard's bench testing, your	24	
25	qualifications and what you did, you followed	25	
	Page 335		Page 337
1	appropriate methodology to assess their bench	1	STATE OF CALIFORNIA )
2	testing?	2	COUNTY OF SANTA BARBARA ) 88.
3	A I did, and I used that methodology when	3	
4	I consult for medical implant companies, assessing	4	I, MONICA T. CORLEY, RMR, CRR, CSR No. 8803,
5	their testing and interpreting it and advising	5	in and for the State of California, do hereby certify:
6	them whether it's being done adequately or	6	That, prior to being examined, the witness
7	whether improvements to the testing should be	7 8	named in the foregoing deposition was by me duly sworn to testify the truth, the whole truth and nothing but
8	undertaken.	9	the truth;
9	Q And in this case you determined that the	10	That said deposition was taken down by me in
10	testing was inadequate?	11	shorthand at the time and place therein named and
11	A I did.	12	thereafter reduced to typewriting under my direction,
12	Q And that it failed to provide information	13	and the same is a true, correct and complete transcript
13	showing that these filters would fail?	14	of said proceedings;
14	A That's correct.	15	That if the foregoing pertains to the original
15	Q Okay. That's all I have.	16	transcript of a deposition in a Federal Case, before
16	And that's an opinion you hold to a	17 10	completion of the proceedings, review of the transcript
17	reasonable degree of engineering certainty?	18 19	{ } was { } was not required.  I further certify that I am not interested in
	A I do.	20	the event of the action.
18		21	Witness my hand this 19th day of July,
19	MR. O'CONNOR: Thanks. THE COURT REPORTER: Do you read and sign?		2017.
20	· · · · · · · · · · · · · · · · · · ·	22	
21	MR. O'CONNOR: We'll read and sign.	23	
22	THE WITNESS: I will read and sign.		-19a-JCR
23	THE VIDEOGRAPHER: We are off excuse	24	
24	me. We are off the record at 1729, and this		Certified Shorthand Reporter
25	concludes today's testimony of Robert McMeeking,	25	for the State of California

85 (Pages 334 - 337)

# Robert McMeeking, Ph.D. In Re: Bard IVC Filters Products Liability

Page 3	38 Page 340
1 TO: Mark O'Connor	1 Page Line Change
2 Re: Signature of Deponent Robert McMeeking, Ph.D.	2
3 Date Errata due back at our offices: 08/19/2017	3 Reason for change
4 5 Greetings:	4 Page Line Change
6 The deponent has reserved the right to read and sign	5
Please have the deponent review the attached PDF	6 Reason for change
7 transcript, noting any changes or corrections on the	7 Page Line Change
attached PDF Errata. The deponent may fill out the 8 Errata electronically or print and fill out manually	8
9	9 Reason for change
Once the Errata is signed by the deponent and notarized,	10 Page Line Change
10 please mail it to the offices of Tiffany Alley (below).	11
11	12 Reason for change
When the signed Errata is returned to us, we will seal	13 Page Line Change
12 and forward to the taking attorney to file with the original transcript. We will also send copies of the	14
13 Errata to all ordering parties	15 Reason for change
14	16 PageLine Change
If the signed Errata is not returned within the time	17
15 above, the original transcript may be filed with the	18 Reason for change
court without the signature of the deponent	20
16   17	DEPONENT'S SIGNATURE
18 Please send completed Errata to:	21
19 Veritext Production Facility	Sworn to and subscribed before me this day of
20 11539 Park Woods Circle, Suite 302	22
21 Alpharetta, GA 30005	23
22 (770) 343-9696	23
23 24	24 NOTARY PUBLIC
25	25 My Commission Expires:
Day 20	
Page 33	27
1 ERRATA for ASSIGNMENT #	
2 I, the undersigned, do hereby certify that I have read the	
transcript of my testimony, and that	
3	
4 There are no changes noted	
5 The following changes are noted:	
6  Divinion 4 to Pielo 20/2VeV of the Federal Bules of Civil	
Pursuant to Rule 30(7)(e) of the Federal Rules of Civil 7 Procedure and/or OCGA 9-11-30(e), any changes in form or	
substance which you desire to make to your testimony shall	
8 be entered upon the deposition with a statement of the	
reasons given for making them. To assist you in making any	
9 such corrections, please use the form below. If additional	
pages are necessary, please furnish same and attach.	25
10	
11 Page Line Change	
12 Person for shares	-
13 Reason for change	•
14 Page Line Change	
16 Reason for change	
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# **EXHIBIT C**

# In The Matter Of: NEWTON v.

BARD

# ROBERT MAXWELL MCMEEKING, PH.D. May 24, 2011

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Page 5 (14:05:04-14:05:32) ROBERT MAXWELL MCMEEKING, PH.D., 1 Having been first duly sworn by the 2 Certified Shorthand Reporter, testified as follows: 3 4 **EXAMINATION** 5 6 BY MS. DALY: Q Dr. McMeeking, I'm Taylor Daly. We met earlier 7 today, and you sat through the deposition of your colleague, Dr. Begley? 9 10 A Yes. Q You were present when we talked about -- at the 11 12 beginning of his deposition -- trying to efficiently take your deposition, and you and he presented a joint report; 13 correct? 14 A That's correct. 15 16 O And what we discussed was that you would try to take some notes and you would be able to then add to any 17 of the questions that I ask Dr. Begley, correct anything that he said that you thought should be different, and so 19

on; correct? A Correct. 21

20

10

O My intent is not to shortcut your deposition; 22 rather, it is to be efficient. So please feel free that 23 you can answer any of the questions as fully as you want.

I'm not holding you to what Dr. Begley said in any way.

(14:08:02-14:08:46)

1 and the FDA. They are balloon expandable and they use the Nitinol behavior specifically in the way that they're

implanted into the heart; and in addition, a stent that

is expanded into arteries to clear the stuff that gets

stuck to the wall in -- when the artery is diseased. Q Are the heart valves made of Nitinol themselves, or did you just say they had Nitinol-like memory

characteristics?

A Well, they have Nitinol stents or -- I've 9 forgotten the word for them -- but one component of the

device is Nitinol, and sewn onto the Nitinol are tissues.

Usually they come from pig pericardium, and the tissue functions as the actual occludo that controls the flow of

the blood through the valve. 14

Q For either the stent consulting that you did or 15 16 the heart valve work that you did, did you develop any modeling for those companies that was a part of their 17 design work? 18

A Not as part of the design work, no. 19

Q What was it a part of? 20

A It was a part of the reliability assessment of 21 the valve that was needed both for assurance of the 22

safety and reliability of the device -- not just the 23

valve, but of the device -- and also to take forward to the FDA to obtain licensing of the device for either

(14:06:23-14:07:03)

1 Do you understand that?

A I understand that, yes. 2

Q Very good. Would you tell me, what would you 3 describe as your general expertise?

A My general expertise is mechanical engineering and materials science, more specifically the modeling and analysis of the mechanical and functional behavior of materials and the fairly significant focus on medical devices.

Q What medical device work have you done either as 11 part of litigation or non-litigation consulting?

12 A The one litigation case was a long time ago. It 13 was a failed -- a bicycle broke while the rider was on 14 it. It was 20 years ago. But the balance of my work on 15 medical devices has been consulting for medical device companies. The biggest area has been prosthetic heart 16 valves. In addition, I've done consulting work on some 17 stents for various purposes, and another area that I've 18 worked on is breast implants. 19

Q Have any of the heart valve products or the 20 stent products involved Nitinol use? 21

A Yes. 22

Q Which ones? 23

A There are a couple of heart valves that are in 24 the pre-market stage of being looked at by the companies (14:09:45-14:10:19)

pre-market or eventually full sale activity for the device involved.

Q In that case, did the FDA require the kind of -was an FEA the modeling that you did?

A Well, some of it was FEA modeling. I looked at the way that fluid can lower the devices, I looked at the way that tissue to which the device is sewn or implanted can lower the devices, and looked to the effect of

residual stress that can be present within the device in the case of carbon valves, and looked at all those 10

features in a variety of ways that involved calculations 12 and modeling. Some of it was finite element modeling to

identify the levels of stresses which were involved in 14 the way that the devices function.

15 Q Do you know if the work that you did, the 16 modeling you did, was something that was required by the FDA for clearance of that particular type of device? 17

A Yes, yes. And in some cases, the FDA directed 18 companies to me to carry out that kind of work. 19

20 O And the IVC filters that we're talking about here, you are aware that the FDA has never required that 21

type of modeling; correct? 22

A I'm not aware of what the FDA requires for these 23 24 devices.

Q Following up on that, do you consider yourself 25

Page 7

(14:11:21-14:11:59)

- 1 to be an expert in FDA regulatory approval processes?
- A I guess I'm an expert in part of the process. I
- would not claim that I'm an expert in every single
- feature of the FDA approval process because that involves
- animal modeling, clinical work; it involves a question of
- shelf life, packaging, and also sort of aspects of the --
- how the device will be implanted, used, and operated with
- and so on.
- O Which you don't do? 9
- 10 A Which I don't do, but I'm aware of a great deal of the process because of my involvement in the sector 11
- 12 that involves safety and reliability of the devices.
- Q With respect to the IVC filters, did you review 13 any of the submissions that Bard made to the FDA either 14
- for the permanent or the retrievable recovery filter? 15
- 16 A I read through one 510(k) submission. I don't remember whether it was for the recovery or the other 17
- 18 device, but I did read through a 510(k) submission. Q Was there anything in that 510(k) submission 19
- that informed you in any way that helped you write the 20 report in the case? 21
- 22 A Yes. For example, I read carefully the -- I mean, I read them all carefully -- but I read 23
- specifically the description of the fatigue test that was carried out on that device, the way that the device was

Page 9 (14:14:39-14:14:59)

- 1 your report on page 7?
- A No, all of the material that I've looked at and

Page 11

Page 12

- relied upon is listed on page 7 and, of course, there's also the list of all the Bard reports that --
- O Correct, and I'll ask you that in a minute.
- Have you had a chance to look, actually, at the letter
- from Jack Davis with the list of Bard materials?
- A I haven't looked at it recently, but --
- O Have you looked at it in the past? 9
- 10 A Yes.
- Q Are you able to confirm that's what you 11
- 12
- 13 A Yes.

14

- O And that it was limited to that?
- A It was limited to that. 15
- Q All right. Let me just, for the record, put
- this in. This is Exhibit 5, actually, to your deposition 17
- 18 and be sure we're talking about the same letter and the same list. 19
- A Well, I haven't memorized all the numbers. 20 (Exhibit 5 was marked for identification.) 21
- 22 Q BY MS. DALY: Of course.
- 23 A But it looks consistent with the list of reports
- that we have in our possession and that we have looked 24
- through.

(14:12:55-14:13:33)

and Dr. Begley did?

12

13

Page 10

- 1 placed inside the tube, and the tube was expanded and
- 2 contracted to carry out the fatigue test, and that guided
- me in my thinking as to what would be the appropriate
- things to look at in the modeling and analysis of the
- stresses that can be generated in the device, and also it
- helped me think about what testing should be done to
- 7 obtain further information about the performance of the device.
- Q So some of the -- the testing that you just 9 10 described that you saw in the 510(k), you did use aspects of that when you modeled one or both of the FEAs that you 11
- A When I discussed how we should go about modeling, that did inform my thinking about what we should do, such as, move the end of the arm by one 15 millimeter to simulate the way that loading could occur 16 to the device when it is en vivo. 17

(Exhibit 1 was marked for identification.)

18 Q Okay. Let me show you Exhibit 1 that I've 19 marked for your deposition, which is the Notice of 20 Deposition in this case. And if you would just turn to 21 page 4 that has the list of materials, is there any 22 additional article or publication -- again, other than 23 some major fluids textbook -- that you refer to during 24

the investigation of this matter that is not listed in

(14:15:29-14:16:08)

O There was a memorandum and it's the last item on 2 the list. There was a memorandum by one of plaintiff's

- 3 attorneys whose name is Michael Prascik. Do you remember
- that memo?
- 5 A No, I don't.
- Q Do you remember ever going through that memo to ask him to get you anything in addition that was listed
- on his memo?
- 9 A Sorry, could you repeat the question.
- Q Do you ever recall reviewing that memo and 10
- asking plaintiff's counsel to get you anything else 11 12 listed on that memo that you thought was relevant?
- A Well, I don't remember -- since I don't remember 13
- the memo, I don't remember it that way. What I do 14
- remember is asking plaintiff's counsel to obtain material
- of a specific nature, such as finite element analyses, 16
- descriptions of anything that might relate to how the 17
- 18 device is loaded, and anything else that was related to
- those two issues. 19
- Q Okay. So the list that is part of this letter 20
- 21 from Jack Davis, Exhibit 5, is in response from
- 22 plaintiffs to that sort of general request by you; is 23 that correct?
- 24 A I believe so, yes.
- 25 Q And you don't know what else is out there that

Page 13 (14:16:47-14:17:30) 1 is a Bard document that might fall within the category of what you just described? A Since I haven't seen it, I don't know. Since I haven't seen them, I don't know. Q Do you have any patents? A I have, I think, three. I'm not sure exactly what -- I've forgotten the number, but three or four. 7 Q What do they relate to? A They relate to -- nothing to do with medical 9 devices. One of them is maybe a little bit related which has to do with adhesion, dry adhesion, and the patent surfaces that you would use to make one surface stick to

analyzing manufacturing processes.
 Q So have you ever designed a medical device?

another. The other ones were analytical systems for

16 A No.

13

25

- 17 Q Have you ever done a study of or written an 18 article on an implantable medical device?
- A I -- actually, I forgot to look through my CV to count it, but I think it's two. I have two papers that are on heart valves, and safety and reliability of heart valves, which, of course, are implantable devices.

23 (Exhibits 2 and 3 were marked for identification.)

Q BY MS. DALY: Let me show you what we've marked

(14:19:48-14:20:31)

understanding is of your role as an expert in this filterlitigation?

A My role was to make an assessment of the device in terms of the loads that could be applied to it and to

5 work -- to assess how high the level of stresses would be
6 as a consequence of the kind of loads the device would
7 experience, and to make an assessment of whether there

8 were concerns that that raised as to the safety and9 reliability of the device.

Q Okay. You were not asked to look at any particular plaintiff's filter and come to a conclusion about what had caused that particular fracture in that particular filter?

A Well, I was asked to look at pictures of the 14 devices that had failed, and as Professor Begley 15 mentioned, we did have -- we do have -- we did have 16 one -- I think one filter in our possession which we've 17 looked at visually, and from the pictures that we've 18 looked at, the SEM micrographs that we've looked at, I'm 19 20 certainly able to make an assessment of why the filters failed, and it's quite clear that the filters failed because of fatigue associated with high stresses that 22 23 they were experiencing. 24

Q Are you able to key a particular plaintiff to a particular scenario in your report that that filter

particular scenario in your report that that inter

(14:18:14-14:18:40)

1 as Exhibit 2 and ask you to identify that.

- 2 A That's my curriculum vitae.
- 3 Q Do you believe it's an up-to-date one?
- A Easiest thing is to look at the last page. It's almost up-to-date. There's one or two papers been added to my publications list and maybe one or two lectures or seminars that I've given that have been added more recently than this version.
- 9 Q But don't have anything to do with IVC filters?
- 10 A Nothing to do with IVC filters.
- 11 Q All right. You stated in your report that you 12 have not given trial or deposition testimony in
- 13 litigation in the last four years?
- 14 A Correct.
- 15 Q How about four years before that?
- 16 A Never. I've never the few cases I've been 17 involved in were settled before even depositions were 18 taken.
- 19 Q Very good. I'm going to hand you Exhibit 4,
- 20 actually, to Dr. Begley's deposition, which are two
- 21 billing letters that he provided, one January and one May22 of 2011, and ask you if those are accurate joint billing
- 23 letters for your time at Dr. Begley's?
- 24 A Yes, they are.
- 25 Q Thank you. Will you state what your

Page 14 (14:21:32-14:22:12)

1 failure happened because of that particular scenario?

2 A Only in the sense that we identified ---

3 Professor Begley and I together identified the places
4 where the stresses would be high in the filter as a
5 consequence of the way that they are implanted and the

6 way that they function within the vena cava, and that the
 7 location and the nature of the failure is consistent with

8 the fact that we found the possibility of high stresses

9 in those locations in the filter.

Q Do you intend when you come to trial to go through, for example, Mrs. Newton, and testify to the jury from the SEM where her fractures are and how that relates to your findings?

A I intend to testify in the way that I just
described which is that we made an assessment of where
the high stresses can arise in the device under
assumptions that should reasonably have been made by Bard
when they designed and analyzed the device, and that the
failure that was experienced by Mrs. Newton's filter is

19 failure that was experienced by Mrs. Newton's filter is
20 consistent with the analysis that we carried out and the
21 observations we made of the filter.

Q Did you have an opportunity to look at Dr.Fasching's report?

- 24 A Yes.
  - Q Do you have any criticisms of her findings on

Page 15

25

(14:23:17-14:23:53)

- 1 SEM about what fracture looks like what?
  - A She is, I think, a little too categorical in
- some of the things that she says. For example, she says
- that only two of the failures are directly associated
- with the fact -- or associated with the edge of -- or
- corner of the sheath; whereas, it is my assessment that
- several more, a few more of the fractures, can be
- associated with the fact that the sheath is a component
- that is causing an increase in stresses in the arms of
- the device and that she's, I think, been a little bit too
- tight in the way that she defines association of the
- fractures with the stress raiser at the corner of the
- sheath. 13
- Q All right. We'll go through those in a minute. 14
- 15 Let me ask you generally about the topics that I was
- talking to Dr. Begley about and see if you have any
- additions to that or any corrections to what we were 17
- talking about, and then I want to take those premises and 18
- I want to walk through these individual plaintiffs. 19
- A Okay. 20
- Q Let's talk first about the chamfer issue. You 21
- heard what Dr. Begley said about the chamfer issue? 22
- 23
- O Do you agree with what he said on the issue of 24
- 25 chamfer?

Page 17 (14:26:13-14:27:05)

> Q It's one of the ones on the list in Jack Davis's 1 letter? 2

- 3 A Yes, correct.
  - Q When you said, "The filters we looked at," are

Page 19

Page 20

- you talking about looking at filters by looking at design drawings of filters, as one way to look at it?
- A I mean, looking at the filters both in terms of the design drawings and the SEM images that's in both of the reports, Dr. Ritchie's and Dr. Fasching's.
- Q And then again, like Dr. Begley, the only 10 physical filter you've seen is Mrs. Carnehl's G2? 11
- 12 A Correct.
- Q Did Mrs. Carnehl's filter that you saw inform 13 you in any particular way about Mrs. Carnehl's filter? 14
- A No, because I didn't even look at it under a 15 microscope. I simply -- it was more interesting just to 16 get an idea of the size and feel of the device and its 17 general configuration. 18
- Q Dr. Begley and I were talking about other 19
- scenarios that you all considered as a possibility that 20
- could be scenarios that the filter would be placed in --21
- A Yes. 22
  - Q -- when implanted in a human.
- 24 A Yes.
- 25 Q And would you answer the questions I asked Dr.

Page 18

(14:24:38-14:25:22)

- A I do.
- Q Is there anything you would like to add or
- correct about his testimony on the chamfer issue? 3
- A No.
- Q When we say, "The chamfer issue," does that 5
- cover all of the different discussions that Dr. Begley 6
- and I were having about sharp edges, beveling,
- chamfering?
- A Yes. I'm interpreting the statement that -- the "chamfer" to mean the question of whether the end of the
- sheath is beyeled or flat, whether there is a sharp edge to the sheath where the legs are adjacent to it, or 12
- 13 whether there's a larger radius of curvature at that
- 14 location. So I'm taking it as an all-encompassing
- question regarding the whole geometry in that area. 15 Q And what do you rely on for the statement in the 16
- report that the filter, the recovery filter as 17 manufactured, is not consistent with a spec with respect
- to the chamfer? 19 20 A Well, the ones that -- the filters that we
- looked at all have flat ends to the sheath, which was not 21 reflected in the drawings of the devices that we saw -- I 22
- 23 saw.
- Q Do you know which drawing you were looking at? 24
- A It was a Bard filter. That's all I recollect. 25

(14:27:52-14:28:29)

23

- 1 Begley the same way with respect to the scenario of the
- upper portion of the arms adhering to the side walls and 3 therefore pulling away during respiratory, and the
- 4 loosening of the hooks from the soft tissue causing
- individual legs to go slack and shed their loads? Would
- you answer the same way Dr. Begley did, that you all made
- an assumption about that, but you haven't actually seen
- imaging, either human or animal or cadaver photographs,
- 9 that support that that's a phenomenon that occurs?
- A Well, broadly speaking, I agree with what 10
- 11 Professor Begley said, but I would respond in a slightly different way, which is that we know -- at least I
- know quite a bit about what is likely, what one should 13 14 expect in this situation. And this comes from the great
- 15 deal of experience, if I may say so, I have had with,
- especially, heart valves, which are subject to some of 16 17 the same phenomenon that I'm about to describe.

18 For example, it's -- well, let me back up.

- 19 First of all, there's quite a lot we do know about what happens in an inferior vena cava. There's blood going
- 21 through it; it's pulsatile flow; it does expand and contract, at least in some circumstances, as a
- 22 consequence of a person breathing; and, of course, it's 23
- 24 composed of tissue and cells that lighten the tissue 25
  - wall.

(14:29:39-14:30:23)

Page 21

(14:32:39-14:33:15)

Page 23

And I should comment that I have additional 2 publications, not on medical devices, but on cell mechanics, which remodeling of cells and remodeling of tissue as a consequence of the mechanical effects is one of the features in the topic covered by the paper.

6 So let me go back to answering the question, 7 which is that from my interaction with the heart valve companies, I know very clearly that remodeling goes on as a consequence of the presence of an implantable device leading to endothelization, that you mentioned earlier, 10 so that the tissue and the cells can grow over the device 12 and entrap the device and therefore cause it to move in a manner that's consistent with the motion of the tissue 13 wall; and furthermore, when loads are applied to cells 14 15 and to tissue, that they tend to remodel in such a way as 16 to relax the loads which are being applied to them so that there are all sorts of possibilities as to what can 17 17 happen to the filter when it's implanted in the vena 18 cava, including it being trapped by the wall of the vena 19 cava. It can also perforate the wall of the vena cava 20 21 because of the tendency for tissue to remodel and relax 22 under the loads which are being applied to the tissue.

23 And I should also comment at this stage that the sort of imaging that one can do in a live patient would 24 25 not reveal exactly how the legs are being loaded, whether

- A The way that we did model it is that we undertook finite element analysis using a
- three-dimensional model of one arm, although it was a
- truncated section of one arm, and we imposed a
- displacement on the truncated end of that arm to reflect
- the fact that the rest of the arm would be trapped in the
- vena cava wall and would force that segment of the arm to move in a manner consistent with the motion of the vena
- cava wall.
- 10 Q And what Dr. Begley described about that 3-D FEA -- what variables were put in, whatever you included in the modeling -- do you agree that he was complete in his
- description of that? 13
- A Yes, I agree that he was complete concerning the 14 things that were needed to do that analysis. 15
  - O Okay. What was he not complete about?
- A Well, he didn't model the inelastic -- not the inelastic -- the shape memory behavior of the Nitinol, which was irrelevant to the problem that we were addressing. 20
- Q Okay. With respect to this other thing, the 21 loosening of the hooks in the soft tissue causing the legs to go slack, you all did not do an FEA to 23 demonstrate that?
- A No. 25

24

(14:31:21-14:31:45)

Page 22

(14:34:03-14:34:29)

Page 24

- 1 all six of them are being evenly loaded.
- Q True; you can see position and so on. 2
- A Yes, but the precision by which you can do the 3 imaging would not reveal the question of whether the legs are evenly loaded or not; and therefore, Bard would not know whether all of the legs were equally loaded when in an implanted device. 7

And I should comment that I know this from 8 concerns raised by trying to image heart valves to 9 determine exactly their location and position when 10 they're implanted because that does relate to how they're 11 loaded en vivo, and --12

- O And it's quite variable? 13
- A And it's quite variable. 14
- Q As it probably is with IVCs as well? 15
- A Yes. 16
- And back to my point --17

MR. HARTLEY: Did you finish your answer? 18 THE WITNESS: Yes, I did. 19

#### BY MS. DALY: 20

- Q With respect to the arms adhering to the side 21 walls and pulling the arms outwards --22
- 23
- O -- to what extent did your investigation try to 24 model that?

- Q That is one of the things that I guess Dr.
- Begley called a "possibility" that he was calling out as a red flag?
- A I think he said it was a "probability." He did call it a "possibility" at some stages, but then adjusted
- his description to describe it as a "probability" for the
- reasons that he went through, which is that it's essentially impossible to assure that the legs would all
- be equally loaded. And the only sensible assumption that
- Bard should have made is that only three of the legs 10 would be loaded because three of the legs would keep the 11
- 12 filter in a stable location.
- Q But again, that's an assumption; true? Without 13 testing and without modeling? 14
- A It is an assumption that Bard should have made. 15
- Q But that's not my question to you. With respect 16 to what you just said about "possibility" versus 17
- "probability," that phenomenon is an assumption that you 18
- 19 and Dr. Begley are making?
- 20 A It is an assumption.
- O Okay. And consequently, an assumption -- to 21
- make an assumption be probable, don't you agree from an 22 engineering standpoint you would have to have some
- 23 modeling or some testing? 24
- 25 A No, I disagree. There are many things that one

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NEWTON v. BARD Page 25 Page 27 (14:35:32-14:35:55) (14:38:23-14:38:46) of their heart valves, and that's because they do good 1 has to assume, but one makes the assumptions on a logical basis, does so in a manner which is conservative, and engineering before they take the device to clinical within a reasonable envelope of considerations, trials to test it out. O Are you aware of any IVC filter manufacturers represents a worst case that can arise. For example, you do not go inside a patient and never had a failure? measure their physiology; you don't go inside a patient A I do not have that knowledge. Q The other FEA work that Dr. Begley and I were and measure their tissue mechanical characteristics; you 7 don't go inside a patient and measure in detail the way talking about was the modeling of the wire against the sheath. that the blood flows through a vessel within their body 9 before you implant the device; and therefore, you must 10 A Yes. make assumptions about the conditions which will be met 11 Q Do you agree that he gave me all of the 11 variables, criteria, whatever was put into that model? 12 by the device. 13 Q Correct. 13 A And that is standard engineering procedure. 14 14 Q Do you agree with what he said the findings of Q But it's still an assumption; it's not 15 that were? 15 16 necessarily hard science? 16 A I do, yes. 17 A Engineering is not science, and science is not 17 Q Do you have anything you want to add to that --18 engineering. 18 testing? Q Okay. But it's not necessarily hard 19 A No, except it wasn't testing. 119 Q Modeling, sorry. And you have done no 20 engineering? 20 21 A It is hard engineering. I agree, it's not hard 21 additional testing -- physical testing, bench testing, science, but it is hard engineering. animal testing -- as Dr. Begley has not done, in 22 22 addition? 23 Q And it's not necessarily hard medicine? 23 A No, I -- I'm not -- I am not a doctor. I am not A I have done no additional testing. 24 24 25 claiming to have any knowledge of the ability to practice 25 Q Now, there are some comments in the report, for Page 28 (14:36:39-14:37:15) (14:39:53-14:40:29) medicine, but I do know that medicine is much more like example, on page 2 -engineering than it is -- it's not a science. Medicine 2 And this has previously been marked as Begley's 6. So we'll put a -- make it "6." 3 is --Q Which is something that the medical device A Page 2? 4 O Yeah, page 2. manufacturers have to deal with, isn't it, because it's 5 not an exact science; you would agree with that? 6 A Okay. A I agree with that, yes. 7 O There are couple of places in the report where Q And even person-to-person variations can happen the report talks about deductions about what Bard's that impact medical devices and their usefulness or their considerations were. And here's one at the beginning of helpfulness or their failure; true? your report, portion 2. Quote, "Based on our review of 10 10 A Yes, and those person-to-person variations, the Bard documentation, we deduce that their principal 11 12 within a reasonable level of understanding, are norm; and consideration of in-situ loading pertained to a full therefore, can be anticipated. 13 blockage of the filter due to arrival of a clot in the 13 14 Q Would you agree that despite whatever testing 14 blood flow, thereby inducing tensile strength in the legs one can do to a medical device, until you implant -- if caused by blood pressure. Bard's analysis assumes all 15 15 it's an implantable device -- until you implant it into a 16 legs are sharing an equal fraction of the load. Such an assumption is not conservative." Where do you believe human being, you are not going to have complete 17 17 information about how that device actually does in a 18 you got the information that that was Bard's assumption? 18 19 human? 19 A It was based on a reading of the document and 20 A You will not have complete understanding or 20 the fact that I saw no statements that suggested that 21 knowledge of how it would perform in the human being, but 21 other concerns were uppermost in the minds of those that you can do sufficient preparatory work to ensure that 22 were developing the design and analyzing the behavior of

your -- that the likelihood of being surprised about what happened is very, very, very low. Many of the heart

valve companies that I work with have never had a failure

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the device on the load.

25 you mean that whole list of documents?

Q And when you say, "Reviewing the document," do

ROBERT MAXWELL MCMEEKING, PH.D. - May 24, 2011 **NEWTON v. BARD** Page 29 Page 31 (14:44:08-14:44:29) (14:41:16-14:41:54) A Whole list of documents that are in that letter. A That it was poorly controlled and that the Q And do you know that you don't have all the consequences were -- in terms of what I saw in the 2 documents that were produced in this litigation? documentation, the consequences were not explored in A If you're telling me I don't have all the terms of how that might make the device vulnerable to documents, then I accept that statement. 5 failure. Q And let's talk a minute about other information O Do you know of any plaintiff filter that you 6 would attribute the weld issue to a fracture in that that you reviewed. Have you read any deposition that's 7 been given in this litigation? 8 plaintiff's --8 9 A No. 9 A No. Q And have you talked to anybody who has ever been 10 O Okay. Let's talk about the fluid drag forces 10 for a moment. No, let me go back. with an IVC medical manufacturer or anybody who was 11 formerly with Bard about Bard's process and 12 Was there anything else that you and Dr. Ritchie considerations in the development of the recovery? 13 talked about? 13 A No. 14 A No. 14 Q Have you talked to Scott Robertson? 15 Q Have you talked to Dr. Ritchie about it? 15 16 A I have talked to Dr. Ritchie, yes. 16 A No. Q And to what extent did you all share O Do you know him? 17 17 information? 18 A No. 18 Q Have you talked to any of the other experts who A We discussed the likely nature -- or not the 19 19 likely -- but the deductions about the nature of the have given reports for the plaintiff in this case? 20 20 A No. failures and the fact that they are clearly fatigue 21 21 failures and they clearly indicate high stresses being 22 O And you've read Dr. Fasching's report? 22 present in the device. 23 A Correct. 23 Q Would you agree that of the filters that we have Q Do you know her? 24 24 25 to look at, the plaintiffs' explanted filters, that there A No. 25 Page 32 Page 30 (14:45:16-14:45:56) (14:42:49-14:43:15) 1 are a number of fractures in different areas in the 2 filter? A If you design different areas as immediately adjacent to the sheath -- and I'm using that term

precisely, which means within a few microns of the edge of the sheath -- at the first bend where the arms are moving as you move along the arms away from the sheath, there are failures there; and then in the legs, there are failures mainly down the knee of the hook. So in that

10 sense, I agree that there are failures in different areas 11 of the filter.

Q And when we go through the individual 12 13 plaintiffs, you're going to help me, if you can, tie the fractures that are seen there to your theory of what 15 caused that; okay?

A Yes. 16

Q Okay. You heard Dr. Begley's and my discussion 17 about the welding issue? 18

19 A Yes.

Q Are you critical of the use of welding to put 20 the wires in place in the first place? 21

A Not of -- no, not of welding the wires in the 22 23 first place.

Q So how would you describe your criticism of the 24 welding situation? 25

Q Then let's talk about fluid drag forces. If you 2 look at page 3, the first full paragraph -- and I asked 3 Dr. Begley about this -- the first sentence is, quote, "Fluid drag forces acting on arms and legs during normal unblocked operation were apparently assumed by Bard to be negligible." What is the basis for that?

7 A That there was -- mainly that there was no effort -- in the documentation that I saw -- to analyze 9 the effect of that fluid drag on the arms or the legs and to identify what level of stress might be associated with 11 the fact that there would be drag caused by the blood 12 flowing past the wires.

O And then you all did some analysis or some 13 14 research -- I don't know what you want to call it -- and 15 you came up with a fluid drag force on the wires as small, on the order of one Newton slash "M"? 16

A One Newton per meter, which means that if you 17 18 had an arm of a length one meter, there would be one 19 Newton load applied to it. Yes, but I forgot what the 20 question was.

21 Q The question was, you either researched or did 22 something --

23 A Yes.

24 O -- to come up with that and determine that the drag forces -- sorry, the fluid drag forces on the wires

(14:46:46-14:47:30)

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1 were small?

A Yes. We looked up -- I looked up Batchelor's book on fluid dynamics, found the section on drag caused

by fluid flowing past a circular cylinder, and used the

formulae and the diagrams in that -- in those pages of

the book to deduce that with the velocity of the fluid

involved in the vena cava and its viscosity -- the

viscosity of blood and its other properties that might be

relevant -- that this would be the level of drag that would be imposed on the wire in those circumstances. 10

O Okay. So you're critical of Bard for not considering the level of drag that you found?

12 A I am critical of the fact that they did not consider the drag on the wire, come to their own 14 conclusions about what level that drag force would be, and impose those drag forces on the wire in a model or a 16 finite element calculation to estimate what level of stresses they would produce in the wire.

Q And then, did you all do that, model that drag 19 20 force?

21 A Yes, that's the -- that leads to the number here, one Newton per meter. 22

Q So that's what you did to get that? 23

24 A That's correct, yes.

Q And the impact of that on fatigue is what? 25

Page 33 (14:49:56-14:50:41)

1 that they did would not be adequate to simulate that?

A The respiratory testing as -- just make sure I

understand what you're describing as respiratory testing -- that is the test where the filter is placed in

a tube, and the tube is dilated to expand its diameter

and contract its diameter, and that would not simulate

the effect of pulsatile flow of the blood going past the filter. 8

9 Q How would you do that?

A You would put the filter in the same kind of tube and attach it to a pulsatile flow system, which are very commonly used in heart valve companies because of the fact that the issues are almost identical; you've got pulsatile flow of the blood going through the device opening and closing it, in that case, so such testing devices are quite common. And you would put the tube in 17 the fluid circuit of such a device and carry out tests over many millions of cycles to see what happens. And 18 you would simultaneously dilate and contract the tube.

19 20 One would have to design the protocol for the 21 test accordingly, but I think that's quite easily done. And therefore you would simultaneously apply the dilation 22 23 that's caused by the respiratory action and the pulsatile 24 flow that's associated with the blood moving past the

25 filter.

Page 34

(14:48:24-14:49:02) A Well, the flow in the vena cava is "pulsatile,"

2 which means that about once every second, the blood stops and starts, which means that the loading goes through

cycles, which is the classic circumstance that can cause

fatigue in any system, any engineering mechanical system; and since -- I used to know this number by heart because

of all my heart valve work -- but there's millions of

cycles per second -- per year involved in the circulatory

system and therefore you quickly ramp up very, very, 10 many, many millions of cycles whenever loading is being

caused by the blood circulating within the human body. 11

12 And therefore, even with very low levels of drag force,

one should at least be concerned that they can generate 13 stresses that could lead to fatigue failure, given a long

enough time of implantation. 15 Q Are you of the opinion that the Bard testing, 16

the respiratory diaphragmatic testing that Bard did and 17 submitted to the FDA, did not simulate this sort of 19 force?

A I saw nothing in the documentation I read that 20 indicated that those kind of tests, except animal 21 modeling -- that was the only modeling, filters in 22 animals -- but that's the only testing that I observed 23 would involve drag forces coming from blood flow. 24

Q So you're saying that the respiratory testing

(14:51:25-14:52:08)

Q So that could be done? 1

A It could be done.

Q Okay. Sitting here today, you don't have -- you have not tested an IVC filter in that way?

5 A No.

Q Nor have you modeled a test like that to

determine whether a test like that would tell us more?

A Well, "modeling" is a very broadly defined word,

and I would say we have done modeling because we've 9 calculated drag forces; we've estimated stress levels;

11 and we've looked at diagrams that indicate the number of cycles it would take at those stress levels to fail the

13 device, fail the material in fatigue, and the number of

cycles involved. Although we didn't write it down in the 14 report, the number of cycles involved at the stress 15

levels we estimated are very small, of the order of 16 17 hundreds of thousands.

Q Okay. And having not done the test that you've 18 just talked about, doing the respiration with the flow --19 20 A Yes.

Q -- you are not able to tell me how that would 21 22 come out?

A No, it's true. Well, actually, can I revise my 23 answer? 24

O You can always revise your answer. 25

Page 35

25

(14:52:53-14:53:32)

A Yeah. I know that I can set up the test in such 2 a way that I can make it fail in a thousand cycles, so in

that sense, I do know. But that would not be --

Q Well, you can set up the test, but that might 5 not necessarily be what's happening in the human.

6 A I agree it would not reflect the loading en vivo, but what I'm saying is that one can anticipate the 7 outcome of the test in some circumstances.

9 O But we haven't done it, so we don't know how it would come out? 10

11 A We haven't done it, so we don't know the outcome 12 of the test in other circumstances.

O Okay. Now, let's talk about the three -- we 13 talked about the three-dimensional finite element test, 14 which is the wire against the sheath? 15

16 A The three-dimensional finite element analysis is the arm being displaced on its end. 17

Q And we've talked about that? 18

A Yes. 19

Q And you don't have anything further to add to 20 what Dr. Begley said about that? 21

22 A No.

Q And you don't have anything further to add to 23 what Dr. Begley said about the two-dimensional finite 24 element analysis? 25

Page 37 (14:55:49-14:56:38)

1 the tolerances that were specified in engineering

Page 39

Page 40

drawings to identify the worst case shapes that can arise

and to then analyze the device based on the deductions

that come from such information. But one of the problems

we faced is that such information was not clearly

available from the drawings and the other documentation that we had.

Q Okay. Do you have any reason to believe that these filters as manufactured -- I'm talking about the recovery ones -- had any significant variability over the

course of the manufacturing, one to the next? 11

12 A I have no information regarding that. 13 Q Do you have any information that anything about the manufacturing process, as opposed to the design 14 process, contributed to fractures in these filters? 15

16 A Certainly looking at the SEM micrographs raised serious concerns in my mind because of the gouges, 17 18 because of other marks that were visible on the surface of the wires, that in standard practice one would 19 implicate in the possibility of fatigue failure and 20 therefore do something to eliminate or to assure oneself 21

22 that they, in fact, would not lead to fatigue failure 23 within the time that the device had to operate in

whatever it was being used for. 24

25 Q Are there any of the plaintiff filters -- that

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(14:54:19-14:54:46)

A No. 1

Q Now, if you look at your report, page 4, the top 2 sentence, "We wish to emphasize that it is impossible to accurately quantify the stresses in the implanted device where the wires emanate from the surrounding sheath." 5 What was the reason for that sentence?

A The reason is that the specification of the shape and the design was not clear enough in the documents that we saw to enable the analysis to be carried out in a way that reflected precisely how the device is shaped and how it would be loaded.

O So that's based on the information you had?

A Based on information that we had, right. 13

Q If you had had an exemplar filter, for example? 14

A Well, we did have an exemplar. 15

Q But you couldn't cut that one up because it 16 belonged to somebody? 17

A Yes. 18

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Q If you had had an exemplar that you could do 19 20 with as you wished, would that have informed you further?

A It would have in the sense that we could then 21 analyze that specific example, but one has to be very 22 careful because that doesn't mean that that is a typical example of the device as produced. Therefore, it is 24 better to work from engineering drawings and to utilize

(14:57:36-14:58:21)

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1 we'll look at in a minute -- that you believe fractures occurred from that situation?

A I'm not sure if it's a G2 or recovery, but my recollection is that there's one where the fracture starts from a defect on the surface, at the surface. 5

Q And do you think it's possible with Nitinol wire to ever be completely free of some sort of surface issue?

A It is never possible to be completely free of defects on the surface of any metal or engineering device, but it's certainly possible to reduce the level of defects that were present on the surface of the devices that I saw in the SEM micrographs.

12 Q Are you going to testify about electropolishing? 13 It's not in the report. 14

A I am not going to testify regarding

15 electropolishing, although I can respond to your question 16 by saying that I do know that electropolishing would 17 reduce the level of roughness present on the surface of 18 the material. And I do also know that many medical 19 20 device companies use electropolishing and are very, very, very careful about the surface finish to their devices 21 22 for the reasons that we are discussing.

23 Q Are you going to say that any particular plaintiff's filter fractured due to a lack of 24

electropolishing?

(14:59:22-14:59:54)

- 1 A No.
- 2 Q You heard Dr. Begley talk about the "pre-crack"?
- A Yes. 3
- 4 O Is that what you called it? The sheath issue
- against the wire? Do you have anything to add to that
- description or that opinion? 6
- A No.
- Q What about to the issue of wire-to-wire contact?
- Do you have anything additional to say about that? 9
- 10 A No.
- O Do you know of any of the plaintiff's filters 11
- 12 where you believe that the fracture was a result of
- wire-to-wire fracture? 13
- A To my recollection, and I don't know whether it 14
- 15 was a G2 or a recovery, but one of the fractures is in a 16 location where there is roughness on the surface that
- could be associated with fretting between the wires as 17
- 18 they come into contact.
- Q And I forgot to ask Dr. Begley about that 19
- sentence in your report, about the fretting. 20
- A Yes. 21
- 22 O So would you go through what your analysis was and your conclusion about fretting. 23
- A Well, fretting involves the contact between two 24 surfaces that then move relative to each other and rub 25

Page 41 (15:03:35-15:04:18) Page 43

- 1 stress between the wire and the sheath at the location where the wire can contact the edge of the sheath.
- Q Do you agree that in the past decade, let's say,
- that with respect to implantable medical devices, there
- has been an evolution in improvement in numbers of those?
- A There has been an improvement, but there's
- improvement all the time, and -- but I would say that the
- most dramatic period of improvement was about -- between about 25 years ago and 20 years ago. So that by 10 years
- ago, there was a culture and a requirement -- I should
- 10 back off the word "requirement" -- but there was 11
- certainly a culture and there was the understanding that
- very serious consideration should be given to the
- possibilities that an implantable device could experience 14
- to assess whether it would fail in fatigue during the
- lifetime of its implantation.
- 17 Q And do you agree that the information we get
- from the field from clinicians and even patients who have
- these medical devices implanted help us as engineers and
- 20 as medical device manufacturers to improve our product?
  - A Yes.

21

- Q And actually, that's a very valuable bit of 22
- 23 information for the improvement of products?
  - A Yes. But as Professor Begley stated, you
- 25 shouldn't do the experiment in the human in a manner that

(15:01:44-15:02:28)

- 1 against each other, and that process can generate the
- 2 initiation of fatigue cracks and defect fatigue damage in
- the material which can then eventually fail the device as
- a consequence of the extension of that fatigue damage.
- 5 So ---
- Q And when we go through these, you'll show me if 6
- you see an example that you believe is fretting?
- A Yes.
- Q Is there any other type of testing, other than 9
- what was described by you thus far or by Dr. Begley, that 10
- you are critical of Bard not doing? 11
- A Yes. Although it really sort of amplifies on 12
- what I was saying before. For example, in the kind of 13
- test that I described, one would make sure that only 14
- 15 three legs were hooked into the tube wall, and just as --
- and I can amplify on something else that Professor Begley 16
- said, which is that testing should have been done in 17
- tubes of various diameter within the range of the 18
- diameters of the vena cava that the implant -- the filter 19
- is qualified for and lie within the range of 20
- counter-indications that were specified by Bard. 21
- In particular, I would have wanted to see a test 22 in the largest diameter of vena cava that was allowed 23
- because it is my deduction that that would be the one 24
  - that would lead to the most severe concentration of

(15:04:58-15:05:31)

- places the human at risk when you can readily avoid that 2 risk.
- Q Well, and that's one problem that manufacturers
- of medical devices have in any event is the issue of
- clinical testing; right?
- A Yes. 6
- 7 And there are ethical considerations or
- 8 restrictions for clinical testing; true?
- A Yes. 9
- Q And depending upon the device, there are 10
- sometimes limitations on clinical testing because you 11
- can't get people to do it? 12
- 13 A Yes.
- 14 Q Okay. And at some point, the device has to be
- implanted in people to see how it does? 15
- A I don't think that's true. If you come to the 16 assessment that the device is too great a risk --17
  - Of course.
- A to implant, then one should not proceed. 19
- Q Of course. But in the end -- you can do 20
- whatever testing you do -- we still tend to be informed
- further, beyond whatever type of testing could have been 22
- done, once it's put into the person; true? 23
- 24 A At least in -- yes, I agree.
- 25 Q Okay. Let's look ---

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Page 47 Page 45 (15:18:36-15:19:14) (15:06:09-15:15:59) A Can I just respond? Q All right. You can keep going. A Can you remind me what issues we were talking 2 Q Yes. 3 about? 3 A One would hope that the experience that one has Q We're talking about -- here are the ones that I is a null data set; in other words, that it doesn't fail. 4 believe you talked about. We're talking about the Q That's the goal? 5 chamfer issue; the wire against the sheath; wire against 6 A Yes. wire where it might -- where in your view it could be Q All right. Can we look through Dr. Fasching's caused by the arm stuck in the vessel, expanding; where report, and if you would rather look through Dr. it could be the legs not loading all in a balanced way. Ritchie's report for this, we can do that. A Can I look through Dr. Ritchie's report? 10 A Okay, so, Bloomquist -- again, I don't -- it 10 says, "Recovery," so it should be recovery --Q Sure. Why don't we take a minute. 11 11 Q Right. 12 A Okay, fine. 12 A I would say that both of the arm failures are MS. DALY: Let's take a break. 13 13 VIDEOGRAPHER: We're going off the record, and associated with the fact that there's -- that it's close 14 14 enough to the end of the sheath for that to cause 15 the time is 3:06 p.m. 15 (Break taken.) 16 problems in terms of the level of stress which is 16 generated. In the case of the Carnehl, which is a G2 --17 (Mr. Begley left.) 17 should we just skip over that or is that --18 VIDEOGRAPHER: We are back on the record, and 18 Q We might as well go through them. the time is 3:15 p.m. 19 19 A Okay. So in the case of the G2, I would say BY MS. DALY: 20 20 that Arm 1, as she depicts it, is close enough to the Q Dr. McMeeking, when we took the break, the 21 21 sheath for the raising of the stress by the sheath to be question on the table is if you would go through either 22 22 Dr. Ritchie on Dr. Fasching's -- whichever you prefer to 23 an issue in how that fatigue got started. 23 Q And let me say this one thing while we're on 24 use -- SEM pictures, and I believe you're going through 24 25 this G2. There will be a whole different deposition 25 Dr. Fasching's? Page 48 Page 46 (15:20:00-15:20:50) (15:16:58-15:17:38) A Yes, that's correct. where we talk about G2 ---A Yes, I understand. Q And if you would do two things at once for me. If you would call out anything that she labels those O -- and it's different. But to the extent that pictures that you do not believe the SEM shows or that it's anything that you've already talked about that's the the SEM shows differently; and then if you will also same in this model, go ahead and call that out. plaintiff-by-plaintiff call out any SEM that you think A Okay. I would say that Arm 2 is in the bend location where stresses can be high as a consequence of represents some fracture that you think could be how the arms get loaded. associated with any of the issues you've raised. 8 A Well, I mean, they're all caused by the issues 9 O In the Carnehl? A In the Carnehl. The Ciaburri is a failure -- in that we've raised in the sense that they're all fatigue | 10 10 failures and they're all caused by levels of stress that the Arm 1, as she calls it, is a failure that to me is 11 associated with the raising of the stress by the 12 would cause fatigue. And, you know, we've identified 12 adjacency of the location with the end of the sheath. 13 high stress as an issue that is associated with the 13 design of the filter. For example, it looks to me that 14 Q So sheath wire? 14 the Carnell arm -- I'm not sure if that's a G2 or a --15 A Sheath wire. 15 Q Okay. Q It's a G2. 16 16 A From her report, I can't say anything about the 17 A A G2. But the Carnehl arm could well be 17 fretting because of the surface marks adjacent to the Clark case. 18 18 source of the fatigue. 19 Q Okay. 19 A There's no pictures of where the actual failure What I can say is that, in each of these cases, 20 20 21 I agree with her that the source of the fatigue -- the 21 is. beginning of the fatigue failure is where she says it is, 22 Q Do you remember anything about the Clark case 22 independently? 23 and that then that -- for example, in the case of the 23

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Carnehl one, it's possible that fretting was associated

with the way that that fatigue got started.

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A No.

Q Okay, that's fine.

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(15:21:26-15:21:51)

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A I'd have to refer to Professor Ritchie's report 1 to say anything further.

In the case of the Gray, Arm 1 is adjacent to -the failure is adjacent to the end of the sheath, and I would implicate the effect of the end of the sheath on the way that stresses have been raised and in the shape of failure.

In the case of Arm 2, that's in the bend location where we find the stresses to be high in certain circumstances.

VIDEOGRAPHER: Sorry to interrupt, but I want to point something out. That vehicle parked right over 12 there is reflecting onto our witness, and look at the

MS. DALY: Yeah, let's stop because all of a 15 sudden you're completely -- it looks like you're on a 16 17 beach. We need to move him.

VIDEOGRAPHER: Right. Going off the record. 18 The time is 3:21 p.m. 19

(Discussion held off the record.)

VIDEOGRAPHER: We are back on the record, and 21 22 the time is 3:24 p.m.

THE WITNESS: Shall I keep going?

24 MS. DALY: Yes, thank you.

25 THE WITNESS: I won't say anything about the

Page 49 (15:27:11-15:28:08)

1 certain circumstances.

The Newton case, both of those failures are close enough -- at least in the view that is in Figure 30 of Dr. Fasching's report -- are close enough to the end of the sheath that I would implicate the end of the sheath in the raising of stresses that would initiate the fatigue failure in those cases, but I guess I would prefer to see another picture just to be sure because the perspective in this case is not very good for making that 10 assessment.

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And in the case of the Newton Arm Number 2, it 12 looks to me like there's a defect on the surface which may be a surface mark or something like that from the 13 manufacturing that is associated with the initiation site. So that is one point of relevancy. 15

And in the case of the Stahl, Arm Number 1 --17 there are a lot of broken arms in this case -- Arm Number I has broken where the first bend takes place after the wire has come out of the sheath, and that's one of the locations where we find the stresses to become high in certain circumstances in which the arms can be loaded.

Arm 2 and 3 look to me as if they're in that 23 same location and are subject to the same concern of the stresses being high there in certain circumstances.

I think that's the end, isn't it?

(15:24:59-15:25:53)

- 1 legs because we didn't do anything in the way of stress
- analysis except to point out that the stresses are
- probably -- or not probably -- we would assess them to be
- twice as high as Bard thought them to be, but I don't --
- I can't comment in detail on the leg fractures in any 5 6

BY MS. DALY: 7

Q And your assumption of what Bard thought them to 8 be is based on just the material you have? 9

A Just the material I have, that's right.

The Lindsey recovery, both the arm failures are 12 adjacent to the end of the sheath, and in my assessment are clearly associated with the stress raising that that 13 adjacency caused in the arms.

The Lynch case, the Lynch recovery filter, Arm 1 is a fracture adjacent to the end of the sheath, and in my assessment, the raising of the stress by the end of the sheath where the arm would come into contact with it is implicated in the fatigue and fracture of that arm.

Arm 2 is perhaps marginal in terms of whether 20 it's close enough to the end of the sheath and whether 21 22 it's in the region where the wire bends. Looking at it, 23 as I do now, it looks to me like it's in the region where the arm bends and therefore is in one of the locations where we find stresses to become high in the arms in

Page 50 (15:29:08-15:29:35)

Q Yeah, I think that's right. I'm not keeping 1 2 track.

A I'm looking at exemplars now. 3

Q Thank you very much, that's great. Few more questions. Now, as you described your role as an expert

in this litigation, you said that you were to look at the

- 7 devices to see if there was concern of susceptibility to failure?
- 9 A Yes.

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12

10 Q I think I quoted you right, okay. And you did that as best you could with the material that you had? 11

A Correct.

13 Q Which I will represent to you is not all of the Bard produced materials nor all of the testing that Bard 14 15 did.

A If you say so, I accept that.

16 Q Okay. And which also did not include your 17 review of the failure investigation report of August 2004 that Bard did, once it was reported to them that 19

fractures were occurring; correct? 20

A Can you clarify? Was that included in the list 21 22 of documents?

23 O It was not.

24 Because I have seen some material that indicates 25 that further work was done, given that there had been

(15:30:16-15:30:39)

- 1 failures observed. But I'm not sure if it -- obviously
- 2 it wasn't the document you're talking about.
- 3 Q Right. You have seen, for example, there's a
- 4 summary by a man named Avijit Mukherjee --
- 5 A Yes.
- 6 Q -- that talks about the investigation? But you
- 7 do not have amongst your documents the 199-page
- 8 investigation report?
- 9 A I don't have anything that's 199 pages.
- 10 Q Okay. And also your investigation did not
- 11 include your reading of depositions of Bard personnel?
- 12 A That's correct.
- 13 Q So you were -- your investigation, your
- 14 conclusions, are based on what you had to review;
- 15 correct?
- 16 A That's correct.
- 17 Q And your FEAs, similarly, were done with
- 18 whatever information you had available to you?
- 19 A That's correct.
- 20 Q And FEAs, you would agree, are only as good as
- 21 what you put into them, variable-wise?
- 22 A That's correct, but we do a very good job of
- 23 that, so ---
- 24 Q Correct.
- 25 A If you don't mind me saying so.

Page 53 (15:32:26-15:32:54)

1 stresses were relatively low and not something that would

Page 55

- 2 cause you concern. But the concern is that they did the
- 3 analysis very poorly and they should have done it in a
- 4 much better fashion.
- Q Well, you noticed that -- I think that the --
- 6 that that FEA was not done in-house; right?
  - 7 A Yes.
- 8 Q And do you know that they don't have capability
- 9 to do that in-house, or didn't at the time?
- 10 A You're telling me. I don't know.
- 11 Q But --
- 12 A Can I just comment?
- 13 Q Let me ask this question; then you can. What
- 14 you're saying is that the information that they got, on
- 15 an outside FEA, you didn't think was -- you did not think
- 16 was the right outcome?
- 17 A That's right, yes. The results they got were
- 18 meaningless because the analysis that was done was
- 19 meaningless, but the responsibility lay on the shoulders
- 20 of Bard to direct their consultants to do a job that was
- 21 appropriate for the way that the filter was loaded and
- 22 used.
- 23 Q And you don't know how they relied upon or
- 24 didn't rely upon that particular FEA to which you're
- 25 referring?

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(15:31:09-15:31:32)

- 1 Q If you had wrong information, you could have
- 2 wrong outcome?
- 3 A Yeah, there's a common expression, "Garbage in, 4 garbage out."
- 5 Q Right. And that certain assumptions that you 6 made --
- 7 A Can I amplify that response?
- 8 Q Yes, of course.
- 9 A Which is that, I did look at the finite element
- 10 analysis. Some of it was done either by or for Bard, and
- 11 quite frankly, I was appalled at how poorly it was
- 12 carried out. And it looked to me a case of what I just
- 13 described, "Garbage in, garbage out."
- 14 Q And so you didn't use that data --
- 15 A No.
- 16 Q -- in yours? Okay. And you also testified that
- 17 some things that are --
- 18 A So can I back up and amplify on that response?
- 19 Q Yes.
- 20 A We did not -- I did not -- we did not use the
- 21 results of the inputs or the configurations from those
- 22 finite element analysis; however, what we did do repeated
- 23 one of their analyses in the sense that we moved an arm
- 24 by one millimeter and got radically different results
- 25 from what they obtained in their analysis, in which their

(15:33:50-15:34:11)

- A No, I don't, but it was provided as one of the
- 2 few documents that Bard produced in their activities that
- 3 described finite element analysis of the filter.
- Q But it was done after the recovery filter was taken off the market in 2003, don't you agree?
- 6 A I don't recall the dates, but I did notice it
- 7 was sometime into the period that we're talking about.
- 8 It wasn't right at the beginning.
- 9 Q So if they relied on that or didn't, you don't
- 10 know?
- 11 A I don't know.
- 12 Q Okay. The other thing that you talked about and 13 put into your report, in addition to doing these specific
- 14 FEAs, you also made certain assumptions?
- 15 A Yes
- 16 Q And again, it's the same thing, "Garbage in,
- 17 garbage out." An assumption is only as good as what
- 18 variables you're using for the assumption?
- 19 A That's correct. But as I said, the assumptions
- 20 that we made were quite appropriate, quite sensible, and
- 21 were the assumptions that Bard should have made in their
- 22 assessment of the performance of the filter, and they
- 23 should have done that before they started implanting it in human beings.
  - If they didn't have finite element capability 10

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# ROBERT MAXWELL MCMEEKING, PH.D. - May 24, 2011

**NEWTON v. BARD** Page 57 (15:35:08-15:35:35) (15:37:36-15:37:51) 1 years ago - is that the date we're talking about? Could 1 analyses that were, in that sense, consistent with the 2 you clarify? If they didn't have finite element common view as to what was going on in the vena cava. capability 10 years ago, they should have because by then 3 Although, I'm not saying that Bard did 4 it was a very mature technology; it was commonly everything they should have done. I'm just saying it was consistent with what we saw in Bard documentation and in available to engineers and companies; and it was not an 5 expensive system to bring in-house and train people to 6 the papers. 7 MS. DALY: And with respect to that one thing -use. By then, it was quite easy to use it in a reliable way, as long as the supervision of what was done was sorry to break in on you. knowledgeable, by which I mean, that the engineers in 9 **FURTHER EXAMINATION** charge should know what it is they're trying to do, and 10 10 BY MS. DALY: do it, and direct the analyst to do it properly. 11 11 12 O And I'm not saying that they didn't do it or 12 Q With respect to that one thing -- after this they didn't have it. I'm just saying, my question was, deposition when you get a chance to go back to your 13 the FEA materials you did look at -- I'll tell you they office, are you able to look at those materials and tell me which document or documents it is that you were 15 were after the date the recovery was taken off the 15 market -- so you don't know to what extent they relied on describing, for that particular issue, that you used? 16 16 A I can. that for what purpose? 17 17 18 A No, I don't. 18 Q And just let Dean know. That would be very Okay. And you don't know, because you haven't 19 helpful. 19 seen it, what other analyses they may have done before 20 A Yes, I can and will. Yes. 20 they put the recovery on the market; fair enough? MS. DALY: Thank you. 21 21 A Well, I accept what you're telling me, but what 22 22 23 **FURTHER EXAMINATION** 23 I can say is that we asked the plaintiff's lawyers to BY MR. HARTLEY: seek all finite element analysis that was carried out on 24 the filters. And that's -- the few documents we received 25 Q You indicated during your testimony that you Page 58 (15:38:52-15:39:39) (15:36:19-15:36:52) is all that we got.

Q And testing, you asked for testing too, didn't you? 3

A Yeah.

Q Okay. Is it your intention to do any physical testing of this filter? 6

A No.

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MS. DALY: That's all I have, thank you.

## **FURTHER EXAMINATION** BY MR. HARTLEY:

Q Doctor, you made notes during Dr. Begley's deposition. Is there anything on your notes that you didn't get an opportunity to discuss with Ms. Daly?

14 A We -- I took care of everything that I noted, 16 except one comment which is that when we made assessments of how we should load the arm in our finite element 18 analysis and our consideration of the loading of the device, we took information from Bard's documentation and 19 20 we looked at those papers that you mentioned, that we were referred to in our list of materials relied upon, 21 22 and I made the assessment that what we did, what we were 23 going to do, what was in those papers, and what Bard was saying was happening in the vena cava were all consistent. And so we carried out finite element

were surprised, I guess, at what your analysis

demonstrated in light of the stresses that were put on that filter. Had you been implored by Bard before they

brought the filter to market, what would you have advised

them, Professor?

A I would have advised them to consider two possible routes: One would be to redesign the filter, by, for example, specifying and ensuring that a radius at the edge of the sheath was chosen that would be benign in terms of the stresses that would be generated in the arms 10 that were subject to loading within the device. 11

And I suppose if the decision was made not to redesign the device, which I would say would be the wrong decision -- and let me back up. There would be other design changes that would be possible, such as changing the diameter of the wires, possibly putting a spacer inside the sheath to keep the wires away from the sheath where they come out of the sheath; one could redesign the shape of the arms to try and reduce the level of stresses that would arise in the circumstances that we were concerned about; and there's other design changes that one could think of making.

23 But if, let's say, there was a decision made not 24 to change the design for some reason, which, as I said, I would say is the wrong decision, then a more extensive

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(15:40:40-15:41:27)

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- 1 effort of testing would be appropriate in the preclinical 2 setting. I'm not saying our models, but in the
- preclinical setting in the lab to find out whether the
- device was going to be subject to premature fatigue
- failures as a consequence of certain things that we're

concerned about. 6

> And I would have advised them to carry out much more complete finite element analysis of the device in its three-dimensional shape to get a clear understanding of what the levels of stress are in the device when it experiences certain circumstances such as the ones that we described: The arms being trapped in the vena cava wall; only three legs being properly embedded in the vena cava wall to support the filter in place.

Q Given what you found in your analysis, had Bard 15 done a more robust analysis of their recovery filter, even the elementary level that you all did in this

litigation, should Bard have been surprised that the 18 recovery filter was failing? 19

A If they had done even the more elementary things 20 21 that we did without even going to finite element 22 analysis, if they had simply did what we call "bean theory" modeling of the loading of the arms and then used standard books to look up stress concentration factors 24 that could arise at the critical locations in the design

(15:44:18-15:44:56)

1 the failures are caused by fatigue from the same sources that we've been talking about today.

Q Do you agree with Dr. Begley that the Bard recovery filter was defectively designed?

A Yes, I do.

Q Do you have an opinion as to whether it was 6 defectively manufactured?

8 A I think that's more difficult to say in that it's not obvious that the surface texturing was a very big problem in the way that the devices failed; however, I would say that the surface quality was very poor and an engineer would have -- with any sort of experience in the effect of surface texture on the reliability and fatigue life of a device -- they would take steps to improve the quality of the surface. 15

Q Let me ask you this question then. Can you say 17 that it's more probable than not that the surface finish contributed to the problems that we see with the recovery 18 filter in the fractures?

A Yes, it's more probable than not.

Q All right. One final question. You've been asked about numerous other analyses that Bard's done that 22 you may or may not have seen, that may or may not be in existence. Regardless of any analysis that Bard has done of the filter, in addition to whatever you've seen, did

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(15:42:30-15:43:14)

1 of the filter, if they had even done that, they would have expected to see premature fatigue failures when the

device was implanted.

O You've mentioned "fatigue failures," and that's what Dr. Ritchie has described them as. Does your analysis of the stressors that are on the filter support Dr. Ritchie's opinion that it is fatigue that is causing the fracturing of the filter?

A Yes. Our modeling and stress analysis supports not only the fact that it is fatigue that is causing 10 these failures, but it supports -- well, in a sense, this 11 is topological -- but it supports the fact that the 12 failures occur in the locations that they do.

13 Q If we look at the exemplar filter you had an 14 opportunity to review, the SEM, as well as Dr. Ritchie's 15 SEMs, your analysis of the stressors that were on the 17 filter, as well as the design, and even Dr. Fasching's scanning electron microscopy photographs, can you say for the filters that we don't have scanning electron 19 microscopy photographs of, that it was the design of the 20 filter, with the stressors that you've been discussing

21 here today, that more probably than not caused the four 22

23 filters of Mohammed, Evert, Kolenda, and Heidi Smith to fail? 24

A Yes, I agree it's more probable than not that

(15:45:58-15:46:22)

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any of the analysis that they did impact the design of

the filter and its ability to fracture and migrate? A I'm not sure if I understand the question, but can I state it this way, that our observations of the shape of the filter and the drawings that we saw were such that it seemed that no serious analysis had been 7 done on the device that would tell them that this was a bad design. 8

Q Would it be fair to say that if Bard did 9 additional analyses that you haven't seen, that those 10 analyses missed a spot as well as their previous 11 analyses? 12

13 A Yes, because there's nothing that I've seen that suggests that improvements were made to the design to such an extent that it eliminated all the problems we've 15 been talking about. 16

> MR. HARTLEY: Thank you, Doctor. MS. DALY: Dr. McMeeking, a few more.

### **FURTHER EXAMINATION**

BY MS. DALY: 21

Q With respect to the surface condition issue, 22 23 your sort of general comment in the answer to Mr. Hartley's question was that you saw examples of poor 24 25 surface condition? I'm not rephrasing you perfectly

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# ROBERT MAXWELL MCMEEKING, PH.D. - May 24, 2011

	NEWTO	BARD	
	Page 65		Page 67
Ι,	5:46:58-15:47:31)	1 '	5:49:20-15:49:55)
1		1	you agree with me that that would require a full-blown
2	A Yes.	2	retesting to see if any redesign created a problem in a
3	Q Okay. However, when you were going through	3	different area that you hadn't anticipated?
4	these particular filters in the Dr. Fasching's report, I	4	A Absolutely, yes.
5	believe there was one that you said might one arm,	5	MS. DALY: Okay.
6	Newton filter, that might be related to a surface	6	MR. HARTLEY: I have nothing further. Thank
7	problem; correct?	7	you, Doctor.
8	A Yes.	8	MS. DALY: Thank you very much for spending the
9	Q So the surface problem creating a fracture is	9	whole day with me.
10	really on a case-by-case basis; true?	10	VIDEOGRAPHER: This concludes today's deposition
11	A Yes.	11	of Robert Maxwell McMeeking, Ph.D. The number of
12	Q So you were then asked a question of whether you	12	videotapes and DVDs used was one. The time is 3:49 p.m.,
13	could say in a very general sense, more probable than	13	and we are off the record.
14	not, that the fractures in plaintiffs' filters where we	14	MR. HARTLEY: Do you want to read and sign,
15	don't have the filters to look at them were caused by any	15	Doctor?
16	of the things that you testified about today; correct?	16	THE WITNESS: What does that mean?
17	You were asked about that?	17	MR. HARTLEY: It means that she will type up
18	A It is more probable than not that those failures	18	everything we said today. She will then send you a copy
19	were caused by fatigue caused by high stresses from	19	of that, or me a copy. You then have the opportunity to
20	this and/or possibly surface finish, but caused by	20	review what you said to make sure it is accurate.
21	high stresses of the type that we've been talking about	21	MS. DALY: And mostly it's just some technical
22	from the sources that we've identified.	22	term that maybe she doesn't get or
23	Q But without looking at them, you cannot be	23	MR. HARTLEY: Or you can waive the right to read
24	certain?	24	and sign and assume she's going to get it correct.
25	A One cannot be 100 percent certain.	25	THE WITNESS: I think it's best to read and
	-		
	Page 66	_	Page 68
(15	:48:18-15:48:46)		
(15	:48:18-15:48:46)  Q And really, the best way to determine that would	1	sign.
(15 1 2	Q And really, the best way to determine that would be to do the SEM and actually look at it, if we have	2	sign. THE REPORTER: Do I have his address?
(15 1 2 3	Q And really, the best way to determine that would be to do the SEM and actually look at it, if we have them?	2	sign.  THE REPORTER: Do I have his address?  (Discussion held off the record.)
(15 1 2	248:18-15:48:46) Q And really, the best way to determine that would be to do the SEM and actually look at it, if we have them? A Well, no, there's an intermediate step, which is	2 3 4	sign.  THE REPORTER: Do I have his address? (Discussion held off the record.)  MR. HARTLEY: You have 30 days to complete your
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1	I, ELIZABETH A. MOOY, CSR NO. 11281, A Certified	
5	Shorthand Reporter in and for the County of Santa	
6		
7	That, prior to being examined, the witness named	
8		
9	testify the truth, the whole truth, and nothing but the	
10	truth;	
11	That said deposition was taken down by me in	
12	shorthand at the time and place therein named, and	
13	thereafter reduced to typewriting by computer-aided	
14	transcription under my direction.	
15	I further certify that I am not interested in	
16	the event of the action,	
17	WITNESS my hand this day of	
18	2011.	
19		
20		
21		
22	Certified Shorthand Reporter in and for the	
23	County of Santa Barbara, State of California	
24		
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